



CONTROLLED SUBSTANCES BOARD

Contact: Chad Zadrazil (608) 266-0011
Room 121A, 1400 East Washington Avenue, Madison
August 14, 2015

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 of March 24, 2015 (4-8)**
- C. Administrative Matters**
 - 1) Staff Updates
 - 2) Member Introductions
 - a. Doug Englebert – Dep't of Health Services Representative
 - b. Alan Bloom – Pharmacologist
 - c. Yvonne Bellay – Dep't of Agriculture, Trade, and Consumer Protection
 - d. Franklin LaDien – Pharmacy Examining Board Representative
 - e. Gunnar Larson – Psychiatrist
 - f. Patrick Mitchell – Attorney General Designee
 - g. Timothy Westlake – Medical Examining Board Representative
 - h. Jeffrey Miller – Board of Nursing Representative
 - i. Wendy Pietz – Dentistry Examining Board Representative
 - 3) Liaison Appointments **(9-10)**
 - 4) Upcoming Meetings
- D. Board Background and PDMP Changes – Discussion and Consideration**
 - 1) Statutory Powers and Changes **(11-13)**
 - 2) Case Referral Process
 - 3) Special Use Authorization (SUA) Overview **(14-17)**
 - 4) Operations Statistics **(18-20)**
 - 5) PDMP Administrative Rules **(21-26)**
 - 6) Pharmacy Examining Board PDMP Workgroup Motion **(27-29)**
 - 7) Pharmacy Examining Board Compliance Policy Motion **(30-32)**
 - 8) Current State of Interstate PDMP Data Sharing **(33-36)**

9) Current PDMP Grants Projects **(37-49)**

E. Board Goals – Discussion and Consideration (50)

F. Legislation and Rule Matters – Discussion and Consideration (51-)

- 1) CSB 2.39 Relating to Exclusion of Naloxegol **(52-54)**
- 2) Phar 18 Relating to Data Submission to PDMP (Act 199) **(55-56)**
- 3) Phar 18 Relating to Operation of Prescription Drug Monitoring Program (PDMP) **(57)**
- 4) Scope for Amending CSB 3 Relating to Special Use Authorization **(58-59)**
- 5) Scope for Amending Phar 18 Relating to Operation of Prescription Drug Monitoring Program (Act 55) **(60-61)**
- 6) Update on CR 15-007 Relating to Hydrocodone Combination Products
- 7) Update on CR 15-008 Relating to Tramadol
- 8) Update on CR 15-009 Relating to Suvorexant
- 9) Update on Legislation and Possible or Pending Rule-Making Projects

G. 11:00 A.M. - APPEARANCE – Kratom (Mitragynine) Scheduling – Discussion and Consideration (62-171)

H. National Governors Association (NGA) Policy Academy Review – Discussion and Consideration (172-175)

I. Speaking Engagement(s), Travel, or Public Relations Request(s) – Discussion and Consideration

- 1) NASCSA Annual Conference – October 20-23, 2015 – Scottsdale, AZ **(176-179)**

J. Informational Items – Discussion and Consideration

- 1) Acetyl Fentanyl Federal Scheduling **(180-184)**
- 2) Wisconsin Public Radio (WPR) Drug Overdose Story **(185-187)**

K. Discussion and Consideration of Items Received After Preparation of the Agenda:

- 1) Introductions, Announcements, and Recognition
- 2) Presentations of Petition(s) for Summary Suspension
- 3) Presentation of Proposed Stipulation(s), Final Decision(s) and Order(s)
- 4) Presentation of Final Decision and Order(s)
- 5) Informational Item(s)
- 6) DLSC Matters
- 7) Status of Statute and Administrative Rule Matters
- 8) Education and Examination Matters
- 9) Credentialing Matters
- 10) Practice Questions
- 11) Legislation / Administrative Rule Matters
- 12) Liaison Report(s)
- 13) Speaking Engagement(s), Travel, or Public Relations Request(s)
- 14) Consulting with Legal Counsel

L. 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 closing disciplinary investigations with administrative warnings (ss. 19.85 (1)(b), and 440.205, 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.).

M. Credentialing Matters

N. **Case Closures**

- 1) 14 CSB 001 – Safe Harbor Humane Society (**188-190**)

O. Deliberation of Items Received After Preparation of the Agenda

- 1) Monitoring Matters
- 2) Administrative Warnings
- 3) Review of Administrative Warning
- 4) Proposed Stipulations, Final Decisions and Orders
- 5) ALJ Proposed Final Decisions and Orders
- 6) Orders Fixing Costs/Matters Related to Costs
- 7) Petitions for Summary Suspension
- 8) Petitions for Re-hearings
- 9) Complaints
- 10) Credential Issues
- 11) Appearances from Requests Received or Renewed
- 12) Consulting with Legal Counsel

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

Voting on Items Considered or Deliberated on in Closed Session, If Voting is Appropriate

ADJOURNMENT

The next scheduled meeting is December 1, 2015.

**CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
March 24, 2015**

PRESENT: Yvonne Bellay, Doug Englebert, Martin Koch, Franklin LaDien, Gunnar Larson (*Via GoTo Meeting, arrived at 9:32 a.m.*)

EXCUSED: Alan Bloom

STAFF: Dan Williams - Executive Director; Nilajah Madison-Head - Bureau Assistant; Sharon Henes - Administrative Rules Coordinator; and other DSPS Staff

CALL TO ORDER

Doug Englebert called the meeting to order at 9:30 a.m. A quorum was confirmed.

ADOPTION OF AGENDA

MOTION: Martin Koch moved, seconded by Franklin LaDien, to adopt the agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF DECEMBER 18, 2014

(*Gunnar Larson joined the meeting at 9:32 a.m.*)

Amendments to the Minutes:

- *On page 4 of the minutes under Legislation and Rule Matters: "CSB 2.37, Wis. Admin Code, Relating to Scheduling Suvorexant" should read "CSB 2.38" in the title and the motion following.*

MOTION: Franklin LaDien moved, seconded by Martin Koch, to adopt the minutes of December 18, 2014 as amended. Motion carried unanimously.

ADMINISTRATIVE MATTERS

Slate Of Officers

NOMINATION: Franklin LaDien nominated the 2014 slate of officers to continue in 2015.

Dan Williams called for nominations three (3) times.

Nomination carried by unanimous consent.

The 2014 Slate of Officers was reelected to continue in 2015.

2015 OFFICER ELECTION RESULTS	
Board Chair	Doug Englebert
Vice Chair	Alan Bloom
Secretary	Yvonne Bellay

Appointment of Liaisons

The Chair appoints the following members to:

2015 LIAISON APPOINTMENTS	
SUA Liaisons	Alan Bloom, Yvonne Bellay
SCAODA Liaison	Doug Englebert
Legislative Liaison	Doug Englebert (Alternate: Martin Koch)

Delegation of Authority

MOTION: Franklin LaDien moved, seconded by Yvonne Bellay, that the Board delegates authority to the Chair to sign documents on behalf of the Board. In order to carry out duties of the Board, the Chair has the ability to delegate this signature authority to the Board's Executive Director for purposes of facilitating the completion of assignments during or between meetings. Motion carried unanimously.

MOTION: Martin Koch moved, seconded by Gunnar Larson, in order to facilitate the completion of assignments between meetings, the Board delegates its authority by order of succession to the Chair, highest ranking officer, or longest serving member of the Board, to appoint liaisons to the Department where knowledge or experience in the profession is required to carry out the duties of the Board in accordance with the law. Motion carried unanimously.

MOTION: Martin Koch moved, seconded by Franklin LaDien, to authorize the SUA liaisons to review and make approval decisions regarding SUA applications. Furthermore, the Board authorizes DSPS staff to sign SUA permits on behalf of the Board. Motion carried unanimously.

MOTION: Franklin LaDien moved, seconded by Martin Koch, to authorize the SUA liaisons to approve required training or credentialing on behalf of the Board. Motion carried unanimously.

MOTION: Yvonne Bellay moved, seconded by Martin Koch, to delegate authority to the Legislative Liaison(s) to address Board issues related to legislative matters excluding media requests. Motion carried unanimously.

MOTION: Martin Koch moved, seconded by Franklin LaDien, to authorize the SCAODA liaison to vote on behalf of the Board at the State Council on Alcohol and Other Drug Abuse meetings. Motion carried unanimously.

MOTION: Yvonne Bellay moved, seconded by Franklin LaDien, that Board Counsel or another Department attorney is formally authorized to serve as the Board's designee for purposes of Wis. Admin. Code SPS § 1.08(1). Motion carried unanimously

LEGISLATION AND RULE MATTERS

Clearinghouse Report on CR 15-007 Relating to Hydrocodone Combination Products

MOTION: Martin Koch moved, seconded by Gunnar Larson, to accept all Clearinghouse comments for CR 15-007 relating to Hydrocodone combination products. Motion carried unanimously.

MOTION: Yvonne Bellay moved, seconded by Franklin LaDien, to authorize the Chair to approve the Legislative Report and Draft for Clearinghouse Rule CR 15-007 for submission to the Governor's Office and Legislature. Motion carried unanimously.

Clearinghouse Report on CR 15-008 Relating to Tramadol

MOTION: Martin Koch moved, seconded by Gunnar Larson, to accept all Clearinghouse comments for CR 15-008 relating to Tramadol. Motion carried unanimously.

MOTION: Yvonne Bellay moved, seconded by Franklin LaDien, to authorize the Chair to approve the Legislative Report and Draft for Clearinghouse Rule CR 15-008 for submission to the Governor's Office and Legislature. Motion carried unanimously.

Clearinghouse Report on CR 15-009 Relating to Suvorexant

MOTION: Martin Koch moved, seconded by Gunnar Larson, to accept all Clearinghouse comments for CR 15-009 relating to Suvorexant. Motion carried unanimously.

MOTION: Yvonne Bellay moved, seconded by Franklin LaDien, to authorize the Chair to approve the Legislative Report and Draft for Clearinghouse Rule CR 15-009 for submission to the Governor's Office and Legislature. Motion carried unanimously.

Affirmative Action to Exclude Naloxegol from Schedule II

MOTION: Franklin LaDien moved, seconded by Martin Koch, to affirm the exclusion of Naloxegol from Schedule II to take effect on April 1, 2015 to allow for publication in the Administrative Register. Motion carried unanimously.

MOTION: Franklin LaDien moved, seconded by Martin Koch, to approve the Scope Statement relating to exclusion of Naloxegol from Schedule II, for submission to the Governor's Office and publication, and to authorize the Chair to approve the scope for implementation no less than 10 days after publication. Motion carried unanimously.

Proposed CSB Modification Relating to Special Use Authorization

MOTION: Martin Koch moved, seconded by Franklin LaDien, to request DSPS staff draft a Scope Statement revising CSB 3 relating to Special Use Authorization and designate the Chair to approve the Scope for submission to the Governor's Office and publication and approve the Scope for implementation no less than 10 days after publication. Motion carried unanimously.

CLOSED SESSION

MOTION: Franklin LaDien moved, seconded by Martin Koch, to 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 closing disciplinary investigation with administrative warning (ss.19.85(1)(b), Stats. and 440.205, 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.). Doug Englebert, Chair, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Yvonne Bellay-yes, Doug Englebert-yes, Martin Koch-yes, Franklin LaDien-yes, Gunnar Larson-yes. Motion carried unanimously.

The Board convened into Closed Session at 10:38 a.m.

RECONVENE TO OPEN SESSION

MOTION: Franklin LaDien moved, seconded by Martin Koch , to reconvene into open session. Motion carried unanimously.

The Board reconvened into Open Session at 11:36 a.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED ON IN CLOSED SESSION

MOTION: Yvonne Bellay moved, seconded by Franklin LaDien, to affirm all motions made in closed session. Motion carried unanimously.

CREENTIALING MATTERS

Application Review

Jessiffany Canine Services LLC

MOTION: Franklin LaDien moved, seconded by Yvonne Bellay, to table the application for a Special Use Authorization (SUA) to Jessiffany Canine Services LLC pending the receipt of additional information. Motion carried unanimously.

ADJOURNMENT

MOTION: Yvonne Bellay moved, seconded by Martin Koch, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 11:37 a.m.

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Nilajah Madison-Head, Bureau Assistant		2) Date When Request Submitted: 08/05/15											
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: 08/14/15	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Administrative Matters Liaison Appointments											
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A											
10) Describe the issue and action that should be addressed: Board is to review Liaison appointments and make changes as necessary													
11) Authorization <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%; border-bottom: 1px solid black;"><i>Nilajah Madison-Head</i></td> <td style="width: 40%; border-bottom: 1px solid black; text-align: right;"><i>08/05/15</i></td> </tr> <tr> <td style="font-size: small;">Signature of person making this request</td> <td style="text-align: right; font-size: small;">Date</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Supervisor (if required)</td> <td style="border-bottom: 1px solid black; text-align: right;">Date</td> </tr> <tr> <td colspan="2" style="border-bottom: 1px solid black;">Executive Director signature (indicates approval to add post agenda deadline item to agenda)</td> </tr> <tr> <td colspan="2" style="text-align: right;">Date</td> </tr> </table>				<i>Nilajah Madison-Head</i>	<i>08/05/15</i>	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	
<i>Nilajah Madison-Head</i>	<i>08/05/15</i>												
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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.													

2015 LIAISON APPOINTMENTS	
SUA Liaisons	Alan Bloom, Yvonne Bellay
SCAODA Liaison	Doug Englebert
Legislative Liaison	Doug Englebert (<i>Alternate: Martin Koch</i>)

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 8/14/15	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? PDMP Statutory Language - Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: For the Board's consideration, attached is the newly created s. 961.385 of the Wisconsin Statutes. The Board may consider rule-writing based on the language.			

961.385 Prescription drug monitoring program.

(1) In this section:

- (a)** "Administer" has the meaning given in s. 450.01 (1).
- (ac)** "Board" means the controlled substances board.
- (ag)** "Monitored prescription drug" means a substance identified in s. 961.16, 961.18, 961.20, or 961.22 or a drug identified by the board by rule as having a substantial potential for abuse.
- (aj)** "Patient" means an individual for whom a monitored prescription drug is prescribed or to whom a monitored prescription drug is dispensed or administered.
- (aL)** "Pharmacist" means a person licensed by the pharmacy examining board under s. 450.03 or 450.05 or licensed in another state and recognized by this state as a person authorized to engage in the practice of pharmacy in the state in which the person is licensed.
- (an)** "Pharmacy" means a place of practice licensed under s. 450.06 or 450.065.
- (ar)** "Practitioner" has the meaning given in s. 450.01 (17) but does not include a veterinarian licensed under ch. 89.
- (b)** "Prescription order" means an order transmitted orally, electronically, or in writing by a practitioner for a monitored prescription drug for a particular patient.

(2) The board shall establish by rule a program for monitoring the dispensing of monitored prescription drugs. The program shall do all of the following:

- (a)** Require a pharmacy or a practitioner to generate a record documenting each dispensing of a monitored prescription drug at the pharmacy or, if the monitored prescription drug is not dispensed at a pharmacy, by the practitioner and to submit the record to the board, except that the program may not require the generation of a record in any of the following circumstances:
 - 1. A monitored prescription drug is administered directly to a patient.
 - 2. A monitored prescription drug is compounded, packaged, or labeled in preparation for delivery but is not delivered.
 - 3. The prescription order is for a monitored prescription drug that is a substance listed in the schedule in s. 961.22 and is not a narcotic drug, and the prescription order is for a number of doses that is intended to last the patient 7 days or less.
- (b)** Identify specific data elements to be contained in a record documenting the dispensing of a monitored prescription drug, including the method of payment and, subject to sub. (2m), the name recorded under s. 450.11 (1b) (bm). In identifying specific data elements, the board shall consider data elements identified by similar programs in other states and shall ensure, to the extent possible, that records generated by the program are easily shared with other states.

NOTE: Par. (b), as renumbered from s. 450.19 (2) (b) by 2015 Wis. Act 55, is shown as affected by 2013 Wis. Acts 124 and 199 and as merged by the legislative reference bureau under s. 13.92 (2) (i).

- (c)** Specify the persons to whom a record may be disclosed and the circumstances under which the disclosure may occur. The rule promulgated under this paragraph shall comply with s. 146.82, except that the rule shall permit the board to disclose a record generated by the program to relevant state boards and agencies, relevant agencies of other states, and relevant law enforcement agencies, as defined in s. 165.77 (1) (b), including under circumstances indicating suspicious or critically dangerous conduct or practices of a pharmacy, pharmacist, practitioner, or patient. The board shall define what constitutes suspicious or critically dangerous conduct or practices for purposes of the rule promulgated under this paragraph.
- (d)** Specify a secure electronic format for submittal of a record generated under the program and authorize the board to grant a pharmacy or practitioner a waiver of the specified

format.

- (e) Specify a deadline for the submittal of a record to the board.
- (f) Permit the board to refer to the appropriate licensing or regulatory board for discipline, or the appropriate law enforcement agency for investigation and possible prosecution, a pharmacist, pharmacy, or practitioner that fails to comply with rules promulgated under this subsection, including by failure to generate a record that is required by the program.
- (g) Maximize the potential for funding the operation of the program with available federal funding sources.
- (h) Ensure that the program complies with s. 146.82 and 45 CFR part 164, subpart E.

(2m)

- (a) The rules promulgated under sub. (2) may not require that a record submitted to the board before 2 years after April 9, 2014, contain the name recorded under s. 450.11 (1b) (bm).
- (b) After consultation with representatives of licensed pharmacists and pharmacies, and subject to the approval of the secretary of safety and professional services, the board may delay the requirement that a record submitted to the board contain the name recorded under s. 450.11 (1b) (bm) for an additional period beyond the date specified in par. (a).

(3)

- (a) A pharmacy, pharmacist, or practitioner is immune from civil or criminal liability or professional discipline arising from the pharmacy's, pharmacist's, or practitioner's compliance in good faith with this section or with rules promulgated under this section.
- (b) Nothing in this section may be construed to require a pharmacy, pharmacist, or practitioner to obtain, before prescribing or dispensing a monitored prescription drug to a patient, information about the patient that has been collected pursuant to the program established under sub. (2).

- (4)** Records generated under the program under this section are not subject to inspection or copying under s. 19.35.

History: 2009 a. 362; 2011 a. 260 s. 81; 2013 a. 3, 20, 124, 199; 2015 a. 55; 2015 a. 55 ss. 4477, 4737f to 4731k; Stats. 2015 s. 961.385; s. 13.92 (2) (i).

Cross-reference: See also ch. Phar 18, Wis. adm. code.

**State of Wisconsin
Department of Safety & Professional Services**

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3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 8/14/15	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? SUA Overview – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Excerpts of Chapter 961 regarding the Board’s duties.			

SUBCHAPTER III

REGULATION OF MANUFACTURE, DISTRIBUTION, DISPENSING AND POSSESSION OF CONTROLLED SUBSTANCES

961.31 Rules. The pharmacy examining board may promulgate rules relating to the manufacture, distribution and dispensing of controlled substances within this state.

History: 1971 c. 219; 1995 a. 448 s. 231; Stats. 1995 s. 961.31.

Cross-reference: See also ch. Phar 8, Wis. adm. code.

961.32 Possession authorization.

- (1) Persons registered under federal law to manufacture, distribute, dispense or conduct research with controlled substances may possess, manufacture, distribute, dispense or conduct research with those substances in this state to the extent authorized by their federal registration and in conformity with the other provisions of this chapter.
- (2) The following persons need not be registered under federal law to lawfully possess controlled substances in this state:
 - (a) An agent or employee of any registered manufacturer, distributor or dispenser of any controlled substance if the agent or employee is acting in the usual course of the agent's or employee's business or employment;
 - (b) A common or contract carrier or warehouse keeper, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment;
 - (c) An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a schedule V substance.
 - (d) Any person exempted under federal law, or for whom federal registration requirements have been waived.
 - (e) A person actively engaged in the direct operation or implementation of a drug disposal program that is authorized under s. 165.65 (2) or (3) or is authorized under federal law, as defined in s. 165.65 (1) (a).

History: 1971 c. 219, 336; 1983 a. 500 s. 43; 1993 a. 482; 1995 a. 448 s. 232; Stats. 1995 s. 961.32; 2013 a. 198.

A doctor or dentist who dispenses drugs to a patient within the course of professional practice is not subject to criminal liability. *State v. Townsend*, 107 Wis. 2d 24, 318 N.W.2d 361 (1982).

961.335 Special use authorization.

- (1)
 - (a) Upon application the controlled substances board may issue a permit authorizing a person to manufacture, obtain, possess, use, administer, or dispense a controlled substance for purposes of scientific research, instructional activities, chemical analysis, or other special uses, without restriction because of enumeration.
 - (b) Except as provided in par. (c), no person may engage in any activity described under par. (a) without a permit issued under this section.
 - (c)
 1. A person who is actively engaged in the direct operation or implementation of a drug disposal program that is authorized under s. 165.65 (2) or (3) or is authorized under federal law, as defined in s. 165.65 (1) (a), may, without a permit issued under this section, obtain or possess a controlled substance for the purposes of operating and

implementing the drug disposal program.

2. A person who is permitted under federal law to dispose of a controlled substance may, without a permit issued under this section, possess the controlled substance for the purpose of disposing of the controlled substance.
3. An individual who is designated and authorized to receive a permit under this section for a college or university department, research unit, or similar administrative organizational unit, and students, laboratory technicians, research specialists, or chemical analysts under his or her supervision, may, without an additional permit issued under this section, possess and use a controlled substance, for the purposes authorized in the permit received for the department or unit.
- (2) A permit issued under this section shall be valid for one year from the date of issue.
- (3) The fee for a permit under this section shall be an amount determined by the controlled substances board but shall not exceed \$25. No fee may be charged for permits issued to employees of state agencies or institutions.
- (4) Permits issued under this section shall be effective only for and shall specify:
 - (a) The name and address of the permittee.
 - (b) The nature of the project authorized by the permit.
 - (c) The controlled substances to be used in the project, by name if included in schedule I, and by name or schedule if included in any other schedule.
 - (d) Whether dispensing to human subjects is authorized.
- (5) A permit shall be effective only for the person, substances and project specified on its face and for additional projects which derive directly from the stated project. Upon application, a valid permit may be amended to add a further activity or to add further substances or schedules to the project permitted thereunder. The fee for such amendment shall be determined by the controlled substances board but shall not exceed \$5.
- (6) Persons who possess a valid permit issued under this section are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.
- (7) The controlled substances board may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative or other proceeding to identify or to identify to the board the individuals who are the subjects of research for which the authorization was obtained.
- (8) The controlled substances board may promulgate rules relating to the granting of special use permits including, but not limited to, requirements for the keeping and disclosure of records other than those that may be withheld under sub. (7), submissions of protocols, filing of applications and suspension or revocation of permits.

Cross-reference: See also ch. CSB 3, Wis. adm. code.

- (9) The controlled substances board may suspend or revoke a permit upon a finding that there is a violation of the rules of the board.

History: 1971 c. 219; 1975 c. 110, 199; 1977 c. 26; 1995 a. 448 s. 233; Stats. 1995 s. 961.335; 2013 a. 198.

961.337 Drug disposal programs. Nothing in this chapter, or rules promulgated under this chapter, prohibits any of the following:

- (1) The direct operation or implementation of a drug disposal program that is authorized under s. 165.65 (2) or (3) or is authorized under federal law, as defined in s. 165.65 (1) (a).
- (2) The transfer by the ultimate user, or by another person that lawfully possesses the controlled substance or controlled substance analog, of a controlled substance or controlled substance analog to a drug disposal program that has been authorized under s. 165.65 (2) or (3) or is

authorized under federal law, as defined in s. 165.65 (1) (a), and that accepts the controlled substance or controlled substance analog.

History: 2013 a. 198.

961.34 Controlled substances therapeutic research.

(1) Upon the request of any practitioner, the controlled substances board shall aid the practitioner in applying for and processing an investigational drug permit for marijuana under 21 USC 355 (i). If the federal food and drug administration issues an investigational drug permit, the controlled substances board shall approve which pharmacies can distribute the marijuana to patients upon written prescription. Only pharmacies located within hospitals are eligible to receive the marijuana for distribution. The controlled substances board shall also approve which practitioners can write prescriptions for the marijuana.

(2)

(a) Upon the request of any physician, the controlled substances board shall aid the physician in applying for and processing an investigational drug permit under 21 USC 355 (i) for cannabidiol as treatment for a seizure disorder. If the federal food and drug administration issues an investigational drug permit, the controlled substances board shall approve which pharmacies and physicians may dispense cannabidiol to patients.

(b) If cannabidiol is removed from the list of controlled substances, or if cannabidiol is determined not to be a controlled substance, under schedule I of 21 USC 812 (c), the controlled substances board shall approve which pharmacies and physicians may dispense cannabidiol to patients as treatment for a seizure disorder.

History: 1981 c. 193; 1983 a. 189 s. 329 (18); 1985 a. 146 s. 8; 1995 a. 448 ss. 16 to 19; Stats. 1995 s. 961.34; 2013 a. 267.

Reefer Madness: Lighting Up in the Dairyland. Bailey. Wis. Law. Nov. 2014.

961.36 Controlled substances board duties relating to diversion control and prevention, compliance with controlled substances law and advice and assistance.

(1) The controlled substances board shall regularly prepare and make available to state regulatory, licensing and law enforcement agencies descriptive and analytic reports on the potential for diversion and actual patterns and trends of distribution, diversion and abuse within the state of certain controlled substances the board selects that are listed in s. 961.16, 961.18, 961.20 or 961.22.

(1m) At the request of the department of safety and professional services or a board, examining board or affiliated credentialing board in the department of safety and professional services, the controlled substances board shall provide advice and assistance in matters related to the controlled substances law to the department or to the board, examining board or affiliated credentialing board in the department making the request for advice or assistance.

(2) The controlled substances board shall enter into written agreements with local, state and federal agencies to improve the identification of sources of diversion and to improve enforcement of and compliance with this chapter and other laws and regulations pertaining to unlawful conduct involving controlled substances. An agreement must specify the roles and responsibilities of each agency that has information or authority to identify, prevent or control drug diversion and drug abuse. The board shall convene periodic meetings to coordinate a state diversion prevention and control program. The board shall assist and promote cooperation and exchange of information among agencies and with other states and the federal government.

(3) The controlled substances board shall evaluate the outcome of its program under this section and shall annually submit a report to the chief clerk of each house of the legislature, for distribution to the legislature under s. 13.172 (3), on its findings with respect to its effect on distribution and abuse of controlled substances, including recommendations for improving control and prevention of the diversion of controlled substances.

History: 1981 c. 200; 1987 a. 186; 1995 a. 305 ss. 2, 3; 1995 a. 448 s. 234; Stats. 1995 s. 961.36; 1997 a. 35 s. 339; 2011 a. 32.

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 8/14/15	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? PDMP Operations Statistics - Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: For the Board's consideration, attached are statistics regarding the operations of the PDMP.			

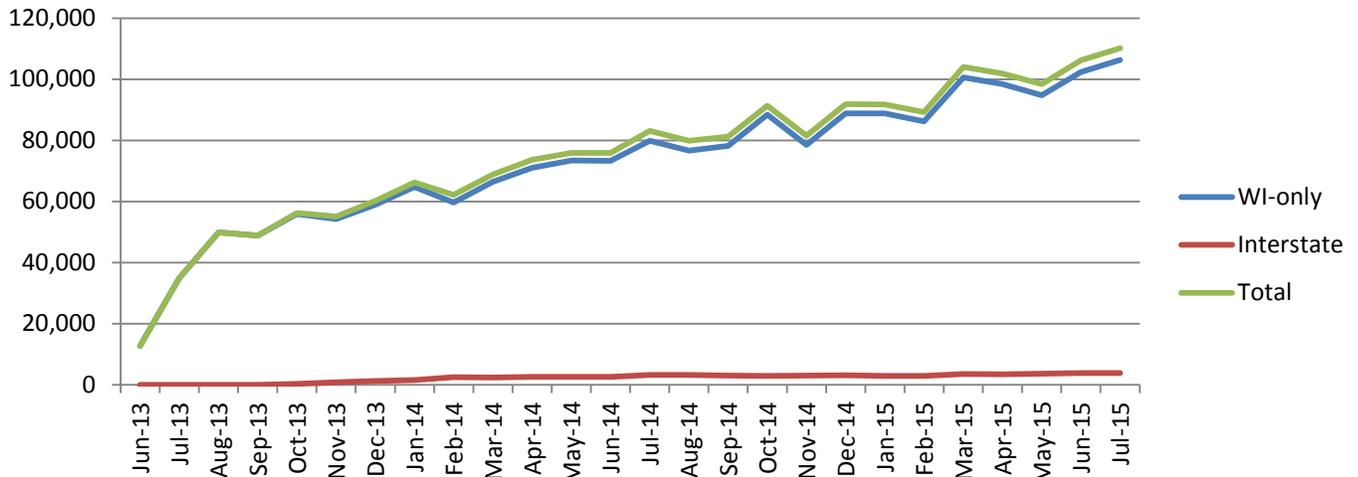


Operational Statistics of the WI PDMP

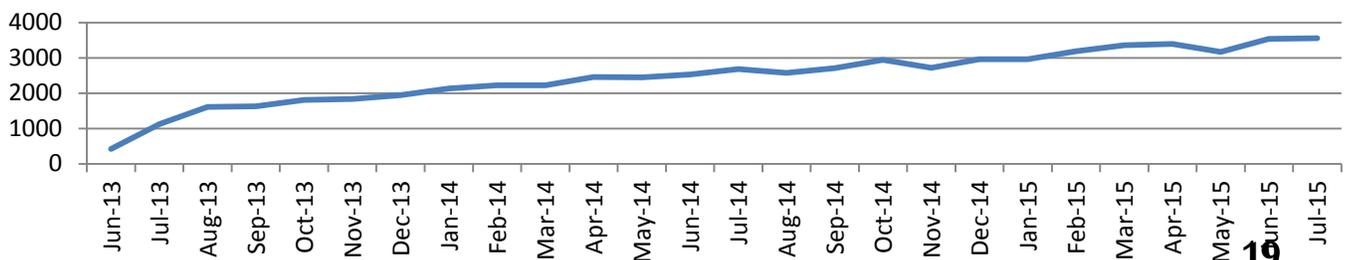
Compiled on August 4, 2015

- Approximately 28 million R_x records in the database
- Approximately 1,800 dispensers actively submitting data
- Approximately 12,420 healthcare users have query accounts
- Healthcare users have created over 1.95 million recipient queries since June 1, 2013
 - In addition, healthcare users have created over 58,000 interstate queries since October 1, 2013
- Healthcare Users have initiated approximately 1,270 PDMP Alerts since July 1, 2013

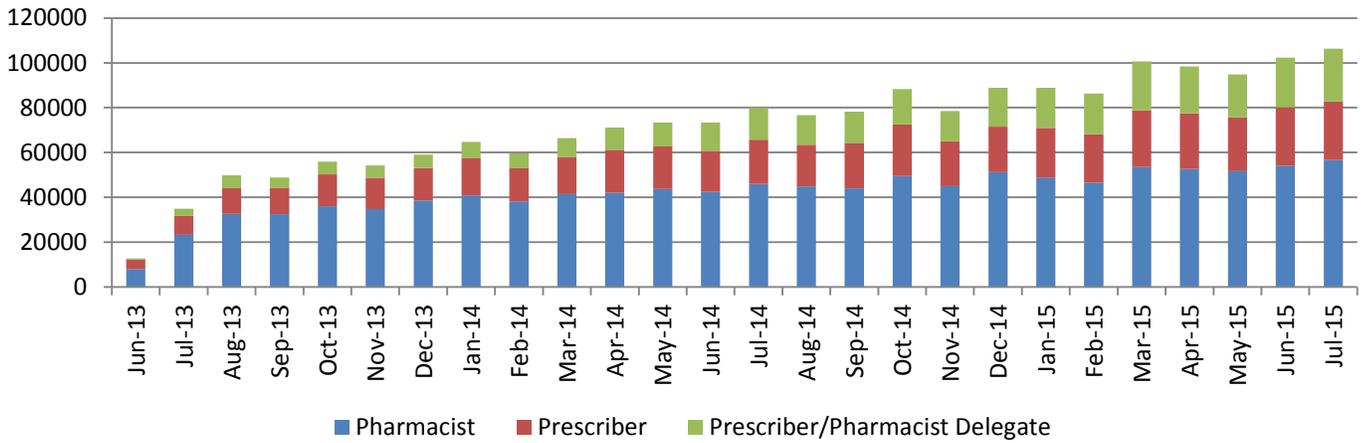
Number of Healthcare Patient Queries Per Month



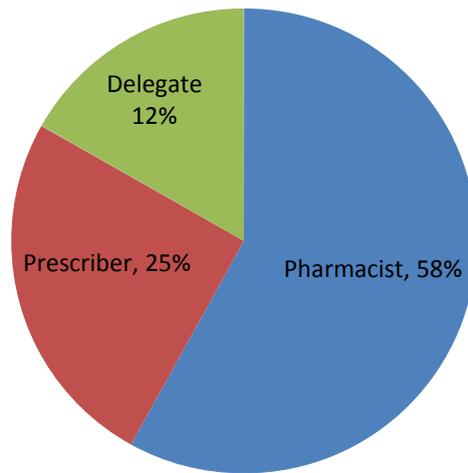
Average Number of Healthcare Patient Queries Per Day



Healthcare Patient Queries Performed by User Group

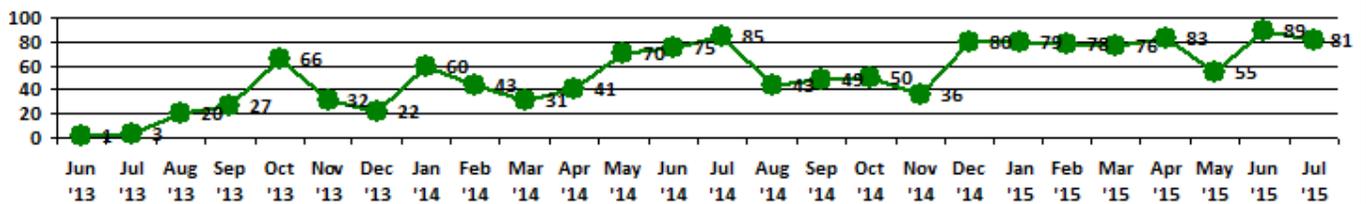


Healthcare Patient Queries Performed by User Group



- Approximately 160 law enforcement and government users with query accounts.
- Law enforcement and government requests:

Requests By Month



**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 8/14/15	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? PDMP Administrative Rules – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: <p>The Administrative Rules governing the PDMP are currently in Chapter Phar 18. I will give the Board an overview of the rules. The Board may consider initiating rule-writing to make changes.</p>			

Chapter Phar 18

PRESCRIPTION DRUG MONITORING PROGRAM

<p>Phar 18.01 Authority and scope. Phar 18.02 Definitions. Phar 18.03 Drugs that have a substantial potential for abuse. Phar 18.04 Compilation of dispensing data. Phar 18.05 Electronic submission of dispensing data. Phar 18.06 Frequency of submissions. Phar 18.07 Correction of dispensing data.</p>	<p>Phar 18.08 Exemptions from compiling and submitting dispensing data. Phar 18.09 Direct access to PDMP information. Phar 18.10 Requests for review. Phar 18.11 Methods of obtaining PDMP information. Phar 18.12 Use of PDMP information by the board and department. Phar 18.13 Confidentiality of PDMP information. Phar 18.14 Exchange of PDMP information.</p>
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Phar 18.01 Authority and scope. The rules in this chapter are adopted under authority in ss. 15.08 (5) (b), 227.11 (2) (a), 961.31, 450.02 (3) (a), and 450.19, Stats., for the purpose of creating a prescription drug monitoring program to collect and maintain information relating to the prescribing and dispensing of prescription drugs.

History: CR 12-009; cr. Register October 2012 No. 682, eff. 1-1-13.

Phar 18.02 Definitions. As used in this chapter:

(1) “Access” means to have the ability to view PDMP information through an account established with the board.
(2) “Administer” has the meaning given in s. 450.01 (1), Stats.
(3) “Animal” has the meaning given in s. 453.02 (1m), Stats.
(3m) “ASAP” means the American Society for Automation in Pharmacy.

Note: Contact: American Society for Automation in Pharmacy, 492 Norristown Road, Suite 160; Blue Bell, PA 19422; phone: (610) 825-7783; fax: (610) 825-7641; webpage: <http://asapnet.org/index.html>.

(4) “Board” has the meaning given in s. 450.01 (2), Stats.
(5) “Controlled substance” means a drug, substance, analog, or precursor described in any of the following:

(a) Schedule I, II, III, IV, or V in the federal controlled substances act, 21 USC 812 (b) (1) to (b) (5) and (c), as changed and updated by 21 CFR 1308.

(b) Schedule I, II, III, IV, or V in subch. II of ch. 961, Stats., as amended by ch. CSB 2.

(6) “Department” means the department of safety and professional services.

(7) “Dispense” has the meaning given in s. 450.01 (7), Stats.

(8) “Dispenser” means all of the following:

(a) A pharmacy.

Note: A site of remote dispensing authorized under s. 450.062, Stats., and s. Phar 7.095 is under the supervision of a pharmacy.

(b) A practitioner who dispenses a monitored prescription drug.

(9) “Dispenser delegate” means any of the following:

(a) A managing pharmacist of a pharmacy.

(b) An agent or employee of a practitioner who has been delegated the task of satisfying the data compilation and submission requirements of ss. Phar 18.04 and Phar 18.05.

(10) “Dispensing data” means data compiled pursuant to s. Phar 18.04.

(11) “Drug” has the meaning given in s. 450.01 (10), Stats.

(11g) “Hospital” has the meaning given in s. 50.33 (2), Stats.

(11r) “Managing pharmacist” has the meaning given in s. Phar 1.02 (6).

(12) (a) “Monitored prescription drug” means all of the following:

1. A controlled substance included in s. 450.19 (1), Stats.

2. A drug identified by the board as having a substantial potential for abuse in s. Phar 18.03.

(b) “Monitored prescription drug” does not mean a controlled substance that by law may be dispensed without a prescription order.

(13) “Patient” has the meaning given in s. 450.01 (14), Stats.

(14) “Person authorized by the patient” means person authorized by the patient in s. 146.81 (5), Stats., and includes persons with delegated authority under s. 48.979, Stats.

(14e) “PDMP” means the Wisconsin prescription drug monitoring program.

(15) “PDMP information” means any of the following:

(a) The data compiled and stored by the board from dispensing data submitted to it by dispensers.

(b) The information created by the board to satisfy the requirements in s. Phar 18.12.

(15g) “Pharmacist” has the meaning given in s. 450.01 (15), Stats.

(15r) “Pharmacist delegate” means an agent of a pharmacist to whom the pharmacist has delegated the task of accessing PDMP information.

(16) “Pharmacy” means any place of practice licensed by the board under ss. 450.06 or 450.065, Stats., including a pharmacy that chooses to solely dispense to animal patients.

(17) “Practitioner” has the meaning given in s. 450.19 (1) (ar), Stats.

(18) “Practitioner delegate” means an agent or employee of a practitioner to whom the practitioner has delegated the task of accessing PDMP information.

(19) “Prescription” has the meaning given in s. 450.01 (19), Stats.

(20) “Prescription order” has the meaning given in s. 450.01 (21), Stats.

(21) “Program” means the prescription drug monitoring program established under this chapter.

(23) “Zero report” means a report that indicates that a dispenser has not dispensed a monitored prescription drug since the previous submission of dispensing data or a zero report.

History: CR 12-009; cr. Register October 2012 No. 682, eff. 1-1-13; correction in (5) (b) made under s. 13.92 (4) (b) 7., Stats., Register October 2012 No. 682; CR 13-065; cr. (3m), (13e), am. (16), (17), r. (22) Register February 2014 No. 698, eff. 3-1-14; (13e) renum. to (14e) under s. 13.92 (4) (b) 1., Stats., Register February 2014 No. 698; correction in (17) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698; CR 14-003; am. (8) (a), renum. (9) to (9) (intro.) and am., cr. (9) (a), (b), (11g), (11r), am. (15) (intro.), cr. (15g), (15r), am. (17) Register August 2014 No. 704, eff. 9-1-14.

Phar 18.03 Drugs that have a substantial potential for abuse. Pursuant to s. 450.19 (1) (ag), Stats., the board has identified all of the following drugs as having a substantial potential for abuse:

(1) A controlled substance identified in schedule II, III, IV or V in the federal controlled substances act, 21 USC 812 (b) (2) to (b) (5) and (c), as changed and updated by 21 CFR 1308.

(2) A controlled substance identified in schedule IV or V in subch. II of ch. 961, Stats., as amended by ch. CSB 2.

(3) Tramadol.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; correction in (2) made under s. 13.92 (4) (b) 7., Stats., Register October 2012 No. 682; CR 13-065: am. (intro.) Register February 2014 No. 698, eff. 3-1-14; correction in (intro.) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698.

Phar 18.04 Compilation of dispensing data. (1) As used in this section:

(a) “DEA registration number” means the registration number issued to a dispenser or practitioner by the federal department of justice, drug enforcement administration.

(b) “Dispenser identifier” means the DEA registration number or when the DEA registration number is not available, the NPI number.

(c) “NDC number” means national drug code number, the universal product identifier used in the U.S. to identify a specific drug product.

(d) “NPI number” means national provider identifier number, the registration number issued to a dispenser or practitioner by the national provider identifier registry.

(e) “Practitioner identifier” means the DEA registration number or when the DEA registration number is not available, the NPI number.

(2) Subject to s. Phar 18.08, a dispenser shall compile dispensing data that contains all of the following information each time the dispenser dispenses a monitored prescription drug:

- (a) The dispenser’s full name.
- (b) The dispenser identifier, if available.
- (c) The date dispensed.
- (d) The prescription number.
- (e) The NDC number or the name and strength of the monitored prescription drug.
- (f) The quantity dispensed.
- (g) The estimated number of days of drug therapy.
- (ge) The classification code for payment type.
- (gm) The number of refills authorized by the prescriber.
- (gs) The refill number of the prescription.
- (h) The practitioner’s full name.
- (i) The practitioner identifier, if available.
- (j) The date prescribed.
- (L) The patient’s full name or if the patient is an animal, the animal’s name and the owner’s last name.
- (m) The patient’s address, or if the patient is an animal, patient’s owner’s address, including street address, city, state, and ZIP code.
- (n) The patient’s date of birth, or if the patient is an animal, patient’s owner’s date of birth.
- (o) The patient’s gender.

(4) A dispenser and dispenser delegate, if applicable, who fail to compile dispensing data as required by sub. (2) may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 13-065: am. (1) (b), (e), (3) (b), (d), (i), (k) Register February 2014 No. 698, eff. 3-1-14; CR 14-003: am. (title), renum. (2) to (2) (intro.) and am., cr. (2) (ge), (gm), (gs), renum. (3) (a) to (g) and (h) to (j) to (2) (a) to (g) and (h) to (j), r. (3) (k), renum. (3) (L) to (o) to (2) (L) to (o) and am. (L) to (n), am. (4) Register August 2014 No. 704, eff. 9-1-14; correction in (2) (intro.) made under s. 35.17, Stats., and in (4) made under s. 13.92 (4) (b) 7., Stats., Register August 2014 No. 704.

Phar 18.05 Electronic submission of dispensing data. (1) Unless exempt under s. Phar 18.08, a dispenser shall electronically submit dispensing data through an account with the board.

Note: The application to create an account may be completed online at www.dsp.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

(2) The dispensing data shall be submitted to the board in compliance with the data standards in the version and release of ASAP implementation guide for prescription monitoring programs identified by the board or other electronic format identified by the board.

Note: The guide for dispensers which specifies the data standards in the version and release of the ASAP implementation guide for prescription monitoring programs identified by the board and other electronic formats identified by the board may be obtained online at www.dsp.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

(3) If a dispenser is not able to create an account or submit dispensing data as required by subs. (1) and (2), the board may grant a waiver to a dispenser who satisfies all of the following conditions:

(a) The dispenser agrees to begin filing dispensing data on a paper form identified by the board for each monitored prescription drug dispensed.

(b) The dispenser files with the board a written application for a waiver on a form provided by the board.

Note: The application for a waiver may be obtained online at www.dsp.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

(4) A dispenser and dispenser delegate, if applicable, who fail to create an account with the board and submit dispensing data as required by subs. (1) and (2) or be granted a waiver under sub. (3) may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 13-065: am. (2) Register February 2014 No. 698, eff. 3-1-14; CR 14-003: am. (1), (4) Register August 2014 No. 704, eff. 9-1-14.

Phar 18.06 Frequency of submissions. (1) A dispenser shall submit dispensing data to the board within 7 days of dispensing a monitored prescription drug.

(2) If a dispenser does not dispense a monitored prescription drug for 7 days, the dispenser shall submit a zero report to the board for each 7-day period during which the dispenser did not dispense a monitored prescription drug.

(3) If a dispenser is not able to submit dispensing data within 7 days of dispensing a monitored prescription drug as required by sub. (1), the board may grant an emergency waiver to a dispenser who satisfies all of the following conditions:

(a) The dispenser is not able to submit dispensing data because of circumstances beyond its control.

(b) The dispenser files with the board a written application for an emergency waiver on a form provided by the board prior to the required submission of dispensing data.

Note: The application for an emergency waiver may be obtained online at www.dsp.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

(4) Unless otherwise specified by the board, an emergency waiver granted under sub. (3) shall only be effective for 7 days.

(5) A dispenser and dispenser delegate, if applicable, who fail to submit dispensing data or a zero report as required by subs. (1) and (2), or be granted an emergency waiver under sub. (3), or a dispenser and a dispenser delegate, if applicable, who submit false information to the board may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 13-065: am. (1), (2), (3) (intro.), r. (4) to (6), (9), renum. (7) to (4) and am., renum. (8) to (5) Register February 2014 No. 698, eff. 3-1-14; CR 14-003: am. (2), (5) Register August 2014 No. 704, eff. 9-1-14.

Phar 18.07 Correction of dispensing data. If a dispenser discovers omissions or inaccuracies in previously submitted dispensing data or other PDMP information, the dispenser shall submit correct information within 7 days.

Note: The written notice to the board may be submitted through an account with the board, sent by electronic mail or sent by U.S. mail to the Department of Safety

and Professional Services 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 14-003: am. Register August 2014 No. 704, eff. 9-1-14.

Phar 18.08 Exemptions from compiling and submitting dispensing data. (1) The board shall exempt a dispenser from compiling and submitting dispensing data and from submitting a zero report as required under this chapter until the dispenser is required to renew his or her license, or until the dispenser dispenses a monitored prescription drug, if the dispenser satisfies all of the following conditions:

(a) The dispenser provides evidence sufficient to the board that the dispenser does not dispense monitored prescription drugs.

(b) The dispenser files with the board a written request for exemption on a form provided by the board.

Note: The application for an exemption may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708. A dispenser who is already exempt can renew his or her exemption as part of the licensure renewal process.

(2) A dispenser is not required to compile or submit dispensing data when the monitored prescription drug is administered directly to a patient.

(3) A dispenser is not required to compile or submit dispensing data when the monitored prescription drug is a substance listed in the schedule in s. 961.22, Stats., and is not a narcotic drug, as defined in s. 961.01 (15), Stats., and is dispensed pursuant to a prescription order for a number of doses that is intended to last the patient 7 days or less.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 14-003: am. (1) (a), cr. (3) Register August 2014 No. 704, eff. 9-1-14.

Phar 18.09 Direct access to PDMP information.

(1) Pharmacists, pharmacist delegates, practitioners, and practitioner delegates may access PDMP information in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records.

(2) To obtain access to PDMP information, pharmacists, pharmacist delegates, practitioners, and practitioner delegates shall do one of the following:

(a) Create an account with the board on a form provided by the board.

(b) Create an account with a prescription monitoring program operated by a relevant agency in another jurisdiction with whom the board exchanges PDMP information pursuant to s. Phar 18.14.

(c) Create an account with a pharmacy or other entity at which pharmacists dispense or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of PDMP information or that is connected to and lawfully obtains data from the state-designated entity under ch. 153, Stats.

(d) Create an account with a hospital or other entity at which practitioners prescribe, dispense, or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of PDMP information or that is connected to and lawfully obtains data from the state-designated entity under ch. 153, Stats.

Note: The application to create an account may be completed online at www.dsps.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

(3) The board may deny, suspend, revoke or otherwise restrict or limit a pharmacist's, pharmacist delegate's, practitioner's, or practitioner delegate's direct access to PDMP information for any of the following reasons:

(a) The pharmacist, pharmacist delegate, practitioner, or practitioner delegate uses PDMP information in violation of s. 146.82 or 450.19, Stats., this chapter, or other state or federal laws or regulations relating to the privacy of patient health care records.

(b) The pharmacist, pharmacist delegate, practitioner, or practitioner delegate is no longer licensed in this state or another state and recognized by this state as a person authorized to prescribe or dispense monitored prescription drugs.

(c) The board, or other licensing board, or regulatory agency takes adverse action against the pharmacist, pharmacist delegate, practitioner, or practitioner delegate.

(d) A licensing board or equivalent regulatory agency in another jurisdiction takes adverse action against the pharmacist, pharmacist delegate, practitioner, or practitioner delegate.

(e) The federal department of justice, drug enforcement administration takes adverse action against the pharmacist, pharmacist delegate, practitioner, or practitioner delegate.

(f) The pharmacist, pharmacist delegate, practitioner, or practitioner delegate is convicted of a crime substantially related to the prescribing or dispensing of a monitored prescription drug.

(g) The pharmacist delegate or practitioner delegate is no longer delegated the task of accessing PDMP information.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 14-003: am. (1), renum. (2) to (2) (intro.) and am., cr. (2) (a) to (d), am. (3) Register August 2014 No. 704, eff. 9-1-14.

Phar 18.10 Requests for review. (1) A pharmacist, pharmacist delegate, practitioner, or practitioner delegate may request that the board review any of the following:

(a) The denial of a waiver requested pursuant to s. Phar 18.05 (3).

(b) The denial of an emergency waiver requested pursuant to s. Phar 18.06 (3).

(c) The denial, suspension, revocation or other restriction or limitation imposed on the dispenser's, dispenser delegate's, practitioner's, or practitioner delegate's account pursuant to s. Phar 18.09 (3).

(2) To request a review, the pharmacist, pharmacist delegate, practitioner, or practitioner delegate shall file a written request with the board within 20 days after the mailing of the notice of the action in sub. (1). The request shall be in writing and include all of the following:

(a) The dispenser's, dispenser delegate's, practitioner's, or practitioner delegate's name and address, including street address, city, state and ZIP code.

(b) The citation to the specific statute or rule on which the request is based.

(3) The board shall conduct the review at its next regularly scheduled meeting and notify the pharmacist, pharmacist delegate, practitioner, or practitioner delegate of the time and place of the review.

(4) No discovery is permitted.

(5) The board shall preside over the review. The review shall be recorded by audio tape unless otherwise specified by the board.

(6) The board shall provide the pharmacist, pharmacist delegate, practitioner, or practitioner delegate with an opportunity to submit written documentation, make a personal appearance before the board and present a statement. The board may establish a time limit for making a presentation. Unless otherwise determined by the board, the time for making a personal appearance shall be 20 minutes.

(7) If the pharmacist, pharmacist delegate, practitioner, or practitioner delegate fails to appear for a review, or withdraws the request for a review, the board may note the failure to appear in the minutes and affirm its original decision without further action.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; correction in (1) (b) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698; CR

14-003: am. (1) (intro.), (2) (intro.), (b), (3), (6), (7) **Register August 2014 No. 704**, eff. 9-1-14.

Phar 18.11 Methods of obtaining PDMP information. (1) The board shall disclose PDMP information about a patient to the patient if he or she does all of the following:

(a) Appears in person at the department with two forms of valid proof of identity, one of which is valid government-issued photographic identification.

(b) Makes a request for the PDMP information on a form provided by the board.

(2) The board shall disclose PDMP information about a patient to a person authorized by the patient if the person authorized by the patient does all of the following:

(a) Appears in person at the department with two forms of valid proof of identity, one of which is valid government-issued photographic identification.

(b) Provides proof sufficient to the board of the authorization or delegation from the patient.

(c) Makes a request for the PDMP information on a form provided by the board.

(5) The board shall disclose the minimum amount of PDMP information necessary to designated staff of a federal or state governmental agency in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the federal or state governmental agency is entitled to the information under s. 146.82 (2) (a) 5., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(6) The board shall disclose the minimum amount of PDMP information necessary to designated staff of the department who is charged with investigating dispensers, dispenser delegates, pharmacists, pharmacist delegates, practitioners, and practitioner delegates in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the department is entitled to the information under s. 146.82 (2) (a) 5., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(7) The board shall disclose the minimum amount of PDMP information necessary to a prisoner's health care provider, the medical staff of a prison or jail in which a prisoner is confined, the receiving institution intake staff at a prison or jail to which a prisoner is being transferred or a person designated by a jailer to maintain prisoner medical records or designated staff of the department of corrections in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the person is entitled to the information under s. 146.82 (2) (a) 21., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(8) The board shall disclose the minimum amount of PDMP information necessary to a coroner, deputy coroner, medical examiner, or medical examiner's assistant following the death of a patient in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the person is entitled to the information under s. 146.82 (2) (a) 18., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(9) The board may disclose de-identified PDMP information which does not and cannot be reasonably used to identify any patient upon written request.

(10) The board shall disclose the minimum amount of PDMP information to designated staff of a law enforcement authority in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides a lawful order of a court of record under s. 146.82 (2) (a) 4., Stats., or provides evidence satisfactory to the board that the law enforcement agency is entitled to the information under s. 146.82 (2) (a) 11., Stats.

(c) Makes a request for PDMP information through its account with the board.

Note: The application to create an account and form to request PDMP information may be completed online at www.dsps.wi.gov or obtained at no charge from the Department of Safety and Professional Services 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

History: CR 12-009: cr. **Register October 2012 No. 682**, eff. 1-1-13; CR 14-003: r. (3), (4), am. (6) (intro.), renun. (9) (intro.) to (9) and am., r. (9) (a) to (c) **Register August 2014 No. 704**, eff. 9-1-14.

Phar 18.12 Use of PDMP information by the board and department. (1) The board shall develop and maintain a PDMP database to store PDMP information.

(2) The PDMP database shall store PDMP information in an encrypted format.

(3) The board shall maintain a log of persons to whom the board grants access to PDMP information.

(4) The board shall maintain a log of information submitted by each dispenser.

(4g) The board shall maintain a log of information accessed by each pharmacist, pharmacist delegate, practitioner, and practitioner delegate.

(4r) The board shall maintain a log of information disclosed, including the name of the person to whom the information was disclosed.

(5) The board shall maintain a log of requests for PDMP information.

(6) Board and department staff assigned administrative duties over the PDMP, vendors, and other agents of the board shall only have access to the minimum amount of PDMP information necessary for all of the following purposes:

(a) The design, implementation, operation, and maintenance of the program, including the PDMP database, as part of the assigned duties and responsibilities of their employment.

(b) The collection of dispensing data as part of the assigned duties and responsibilities under s. 450.19, Stats., and this chapter.

(c) Evaluating and responding to legitimate requests for PDMP information.

(d) Other legally authorized purposes.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 14-003: am. (4), cr. (4g), (4r) Register August 2014 No. 704, eff. 9-1-14.

Phar 18.13 Confidentiality of PDMP information.

(1) The PDMP information maintained by the board, department or a vendor contracting with the department which is submitted to, maintained, or stored as a part of the program is not subject to inspection or copying under s. 19.35, Stats.

(2) A person who discloses PDMP information in violation of s. 146.82 or 450.19, Stats., this chapter, or other state or federal laws or regulations relating to the privacy of patient health care records, may be subject to disciplinary action by the licensing board that issued the license under which the person is authorized to prescribe or dispense monitored prescription drugs and all appropriate civil and criminal penalties.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13.

Phar 18.14 Exchange of PDMP information. (1) The board may exchange PDMP information with a prescription monitoring program operated by a relevant agency in another state or jurisdiction if the prescription monitoring program satisfies all of the following conditions:

(a) The prescription monitoring program is compatible with the program.

(b) The relevant agency operating the prescription monitoring program agrees to exchange similar information with the program.

(2) In determining the compatibility of a prescription monitoring program to the program, the board may consider any of the following:

(a) The safeguards for privacy of patient records and the prescription monitoring program's success in protecting patient privacy.

(b) The persons authorized to access the information stored by the prescription monitoring program.

(c) The schedules of controlled substances monitored by the prescription monitoring program.

(d) The information required by the agency to be submitted regarding the dispensing of a prescription drug.

(e) The costs and benefits to the board of sharing information.

(3) The board may assess a prescription monitoring program's continued compatibility with the program at any time.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; CR 14-003: am. (1) (intro.) Register August 2014 No. 704, eff. 9-1-14.

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 8/14/15	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? PEB PDMP Workgroup Motion– Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: For the Board’s discussion and consideration, the motion of the Pharmacy Examining Board delegating authority to a “PDMP Workgroup” is attached.			

**PHARMACY EXAMINING BOARD
MEETING MINUTES
March 26, 2014**

PRESENT: Thaddeus Schumacher, Charlotte Rasmussen, Franklin LaDien, Terry Maves, Kristi Sullivan, Cathy Winters, Philip Trapskin

ABSENT:

STAFF: Dan Williams-Executive Director; Matthew Guidry-Bureau Assistant, and other Department Staff

CALL TO ORDER

Thaddeus Schumacher called the meeting to order at 9:03 a.m. A quorum of seven (7) members was confirmed.

ADOPTION OF AGENDA

MOTION: Kristi Sullivan moved, seconded by Cathy Winters, to adopt the agenda as published. Motion carried unanimously.

CLEARINGHOUSE RULE 14-023

MOTION: Cathy Winters moved, seconded by Franklin LaDien, to accept all Clearinghouse comments for CR 14-023 relating to council and exam names. Motion carried unanimously.

MOTION: Franklin LaDien moved, seconded by Kristi Sullivan, to authorize the Chair to approve the Legislative Report and Draft for Clearinghouse Rule 14-023 revising Phar 1.02, 7.10, 16.03 for submission to the Governor's Office and Legislature. Motion carried unanimously.

APPROVAL OF MINUTES OF FEBRUARY 12, 2014

MOTION: Terry Maves moved, seconded by Cathy Winters, to approve the minutes of February 12, 2014 as published. Motion carried unanimously.

Terry Maves left the meeting at 9:35 a.m.

PRESCRIPTION DRUG MONITORING PROGRAM UPDATE

MOTION: Cathy Winters moved, seconded by Kristi Sullivan, to authorize the designated PDMP Liaisons to make individual decisions on behalf of the Board when waiting for a Board meeting would unreasonably delay the development, testing, deployment, or operation of the PDMP. Motion carried unanimously.

MOTION: Philip Trapskin moved, seconded by Charlotte Rasmussen, to authorize the designated PDMP staff to refer non-compliant reporting of PDMP dispensing data from pharmacies and, or, pharmacy delegates if appropriate, to the Division of Legal Services and Compliance starting as of July 1, 2014. Motion carried unanimously.

LEGISLATION/ADMINISTRATIVE RULE MATTERS

MOTION: Cathy Winters moved, seconded by Charlotte Rasmussen, to request DSPS staff draft a Scope Statement Phar 4 relating to exams. Motion carried unanimously.

VARIANCE REQUESTS

MOTION: Kristi Sullivan moved, seconded by Cathy Winters, the board accepts the withdrawal of St. Joseph's Community Hospital's request application dated February 11, 2014. Should an updated request be received, the board delegates final decision authority to Philip Trapskin as to the Variance Requests. Motion carried unanimously.

Philip Trapskin recuses himself in the deliberation, discussion, and voting in the matter of the University of Wisconsin Hospital and Clinics request.

Terry Maves has returned to the meeting at 11:25 a.m.

MOTION: Terry Maves moved, seconded by Kristi Sullivan, the board accepts the Withdrawal of the Tech-Check-Tech Variance Request submitted by UW Hospitals and Clinics' application dated March 10, 2014. Should an updated request be received, the Board delegates final decision authority to Cathy Winters as to the Variance request. Motion carried unanimously.

SPEAKING ENGAGEMENT

MOTION: Cathy Winters moved, seconded by Charlotte Rasmussen, to delegate Franklin LaDien to represent the Board at the NABP Annual Meeting on May 17-20, 2014 in Phoenix, Arizona. Motion carried unanimously.

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 8/14/15	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? PDMP Pharmacy Compliance Policy – Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: For the Board’s discussion and consideration, the current PDMP pharmacy compliance policy is attached.			

**PHARMACY EXAMINING BOARD
MEETING MINUTES
February 12, 2014**

PRESENT: Thaddeus Schumacher, Charlotte Rasmussen, Franklin LaDien, Terry Maves, Kristi Sullivan, Cathy Winters, Philip Trapskin

STAFF: Dan Williams, Executive Director; Matthew Guidry, Bureau Assistant; and other Department Staff

CALL TO ORDER

Thaddeus Schumacher; called the meeting to order at 9:10 a.m. A quorum of seven (7) members was confirmed.

ADOPTION OF AGENDA

MOTION: Kristi Sullivan moved, seconded by Cathy Winters, to adopt the agenda as published. Motion carried unanimously.

CLEARINGHOUSE RULE 14-002

MOTION: Cathy Winters moved, seconded by Franklin LaDien, to partially accept 5e, f, g and accept fully all remaining Clearinghouse comments for CR 14-003 relating to PDMP. Motion carried unanimously.

MOTION: Philip Trapskin moved, seconded by Terry Maves, to amend Clearinghouse Rule 14-003 to address public hearing comments by Joe Kachelski and recommended language from Chad Zadrazil. The Board discussed the written comments from Andrew Rich and declines to make changes to allow law enforcement to obtain records from PDMP without a warrant. The Board requests DSPS Staff to draft a Scope Statement related to the public comments received from Angela Studnicka related to dispensing to long term care facilities. Motion carried unanimously

MOTION: Kristi Sullivan moved, seconded by Charlotte Rasmussen, to authorize the Chair, or Chair's designee, to approve the Legislative Report and Draft for Clearinghouse Rule 14-003 revising PHAR 18 for submission to the Governor's Office and Legislature. Motion carried unanimously.

APPROVAL OF MINUTES OF DECEMBER 11, 2013

MOTION: Kristi Sullivan moved, seconded by Franklin LaDien, to approve the minutes of December 11, 2013 as published. Motion carried unanimously.

LEGISLATION/ADMINISTRATIVE RULE MATTERS

- MOTION:** Terry Maves moved, seconded by Charlotte Rasmussen, to authorize the Chair to approve the revisions of PHAR 1, 7, and 16 as amended relating to exam and council names for posting for economic impact comments and submission to the Clearinghouse. The public hearing will take place on March 26, 2014. Motion carried unanimously.
- MOTION:** Kristi Sullivan moved, seconded by Franklin LaDien, to request DSPS staff amend Scope Statement revising PHAR 2 ,4 to include Act 114 relating to licensure and exams and designate the Chair to advise DSPS staff. Motion carried unanimously.
- MOTION:** Charlotte Rasmussen moved, seconded by Kristi Sullivan, to create a committee of the Board charged with revisions to PHAR 15 and appoint Thaddeus Schumacher, Philip Trapskin and Franklin LaDien as committee members. Motion carried unanimously.

VARIANCE REPORTS

- MOTION:** Philip Trapskin moved, seconded by Franklin LaDien, to accept all Tech-Check-Tech Variance Reports. Motion carried unanimously.
- MOTION:** Philip Trapskin moved, seconded by Charlotte Rasmussen, to accept all Ratio Variance Reports. Motion carried unanimously.
- MOTION:** Philip Trapskin moved, seconded by Kristi Sullivan, to accept all Robotic Variance Reports. Motion carried unanimously.

PRESCRIPTION DRUG MONITORING PROGRAM

- MOTION:** Cathy Winters moved, seconded by Charlotte Rasmussen, to address compliance issues with the PDMP program, DSPS Staff is delegated the authority to send a letter to gain compliance, and if compliance is not gained the dispenser will be referred to the Board screening panel. Motion carried unanimously.

BOARD INFORMATIONAL ITEMS

- MOTION:** Franklin LaDien moved, seconded by Terry Maves, to send the Iowa investigation materials to the screening panel for further review. Motion carried unanimously.
- MOTION:** Philip Trapskin moved, seconded by Kristi Sullivan, to request DSPS staff to research the resources in other states to determine how Wisconsin benchmarks related to pharmacy inspection frequency, training, credentials, and budgets. Motion carried unanimously.

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 8/14/15	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Interstate PDMP Data– Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: <p>For the Board’s consideration, attached is information about the WI PDMP’s connection to the National Association of Boards of Pharmacy PMP InterConnect. The Board may consider changes to the WI PDMP’s connection and states with which it shares PDMP data.</p>			



NABP PMP InterConnect

Developed by the National Association of Boards of Pharmacy® (NABP®), NABP PMP InterConnect® was designed to facilitate interoperability and interstate data sharing between state prescription monitoring programs (PMPs). The system was created at the request of several state PMPs to address a number of roadblocks states were experiencing in implementing a PMP data sharing solution. By enabling PMPs across the United States to be linked, PMP InterConnect provides a more effective means of combating drug diversion and drug abuse nationwide.



■ How it works:

- As a “rules engine” PMP InterConnect ensures that each participating state’s data access rules are enforced every time a request to the system is made.
- All data are encrypted and no data are stored in PMP InterConnect.
- To further ensure that the process remains time and cost efficient, PMPs choosing to participate need only enter into a single memorandum of understanding (MOU) with NABP rather than having to develop separate contractual agreements with each participating PMP.

■ State Participation:

- The system became operational with data exchanges between Indiana and Ohio in August 2011.
- As of May 2015, 29 states are live.

■ Governance:

- PMP InterConnect is governed by a Steering Committee composed exclusively of representatives of the PMPs that are participating in the system or have executed an MOU to participate.
- The Steering Committee serves as the governing and advisory body as it relates to the administration and function of PMP InterConnect. No outside organization,

public or private, has direct access to PMP InterConnect, a vote about, influence over, or the ability to direct the administration and function of PMP InterConnect.

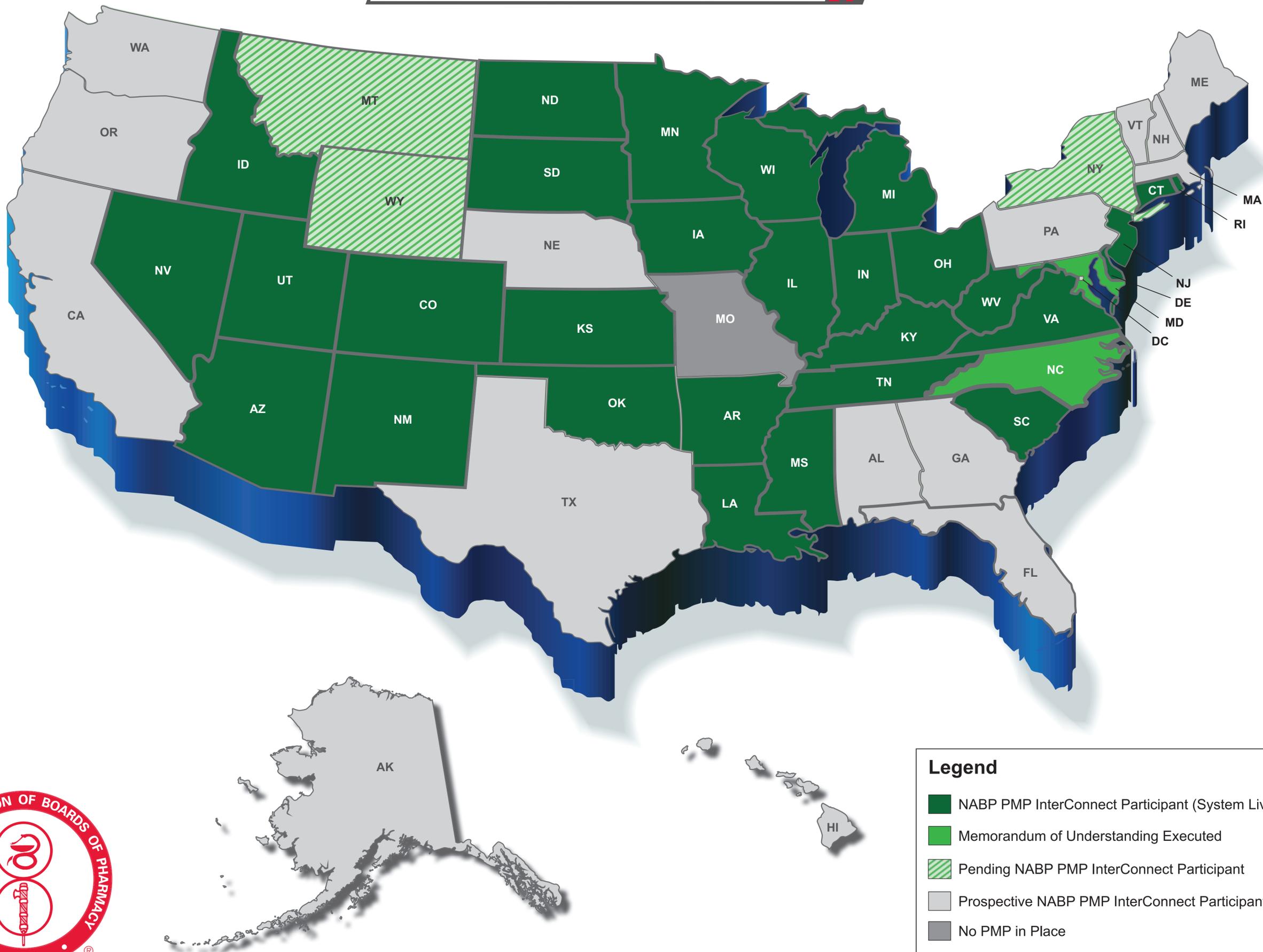
■ Cost/Funding:

- NABP has paid all costs associated with the development and implementation of PMP InterConnect and will pay for each participating PMP through June 2016 using, exclusively, its own revenues derived from program resources. NABP recognizes the financial constraints faced by states and believes this project is a logical place to assist in addressing prescription drug abuse.
- In 2011, NABP received an unrestricted educational grant from Purdue Pharma L.P. Those funds were used for states that needed financial assistance to modify its PMP software to participate in PMP InterConnect. This educational grant was not used for any costs associated with the development, implementation, or ongoing operational costs of PMP InterConnect.

■ More Information:

- Additional information about PMP InterConnect, including the most up-to-date information on state participation, is available in the Programs section of the NABP website at www.nabp.net.

PMP INTERCONNECT®



Legend

- NABP PMP InterConnect Participant (System Live)
- Memorandum of Understanding Executed
- Pending NABP PMP InterConnect Participant
- Prospective NABP PMP InterConnect Participant
- No PMP in Place

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 8/14/15	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? PDMP Grant Projects- Informational	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: For the Board's information, attached is information about the current grant-funded projects related to the PDMP.			



WI PRESCRIPTION DRUG MONITORING PROGRAM

Controlled Substances Board Meeting

August 14, 2015

PDMP Data Integration

- SAMHSA PDMP-EHR Data Integration Grant Project
- S&I Framework PDMP-HIT Integration Effort
- U.S. Department of Veterans Affairs Pilot Project

SAMHSA Grant Background

- 2 Cohorts:
 - 2012: FL, IL, IN, KS, ME, OH, TX, WA, WV
 - 2013: KY, MA, NY, ND, RI, SC, WI
- 2013 Cohort:
 - 2-year awards
 - \$212,500 per year limit



Grant Objectives

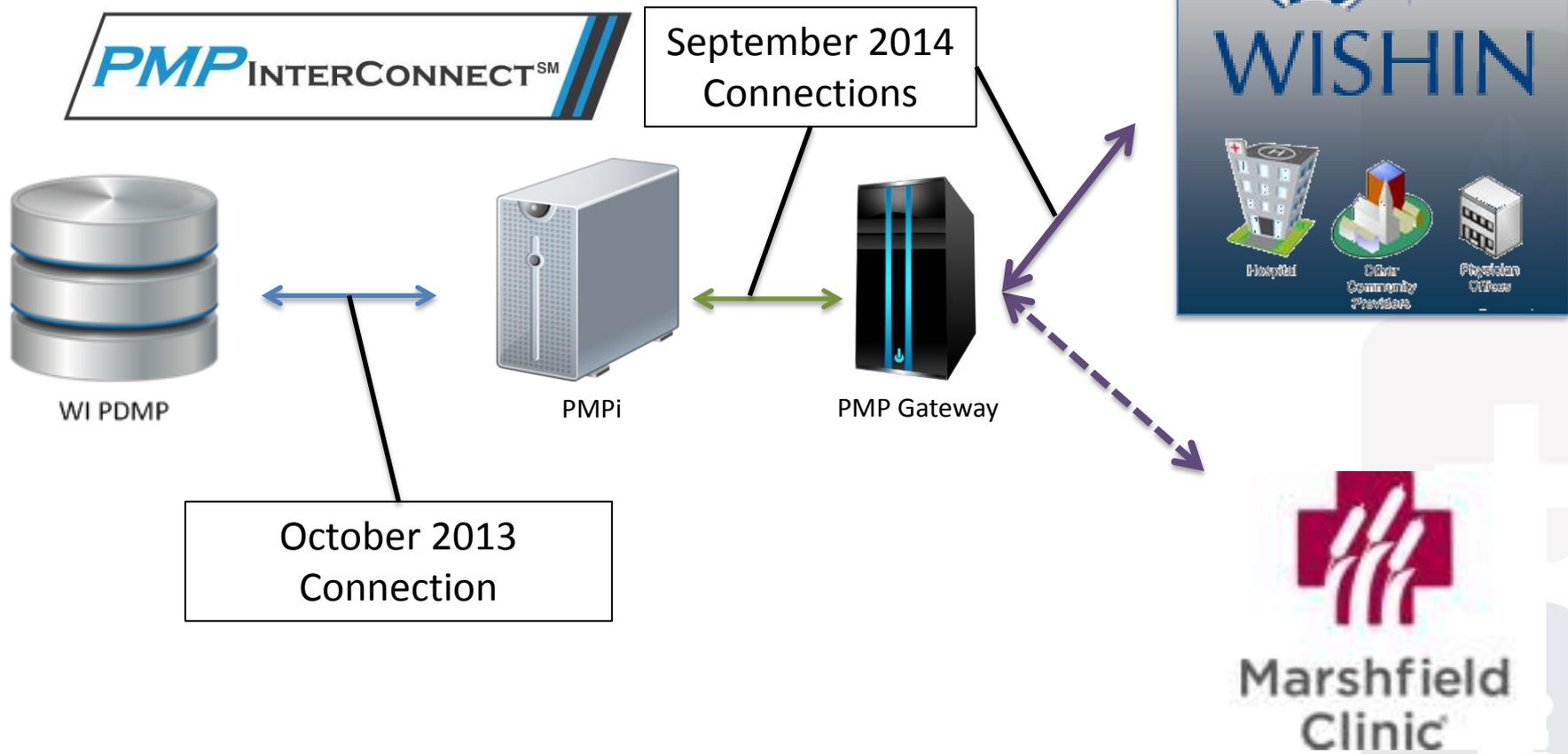
To foster the ability of states to reduce the nature, scope, and extent of prescription drug abuse, SAMHSA expects grantees to:

1. improve the quality of prescription drug information available to healthcare providers by **integrating PDMP data into existing technologies**, e.g., EHRs, Health Information Exchanges (HIEs); and
2. support real-time access to prescription drug information by **integrating PDMP data into existing clinical workflows**. Grant funds will assist states in addressing prescription drug misuse and abuse strategies by integrating their PDMP data into EHRs and other Health Information Technology (HIT) systems. These grant funds cannot be used to enhance or expand PDMPs and can only be used for the purposes of integrating PDMP data into health information systems.

WI SAMHSA Project Scope

- Total Award: \$387,820
- Project Period: 9/30/2013 - **9/29/2016**
- WI PDMP data must be viewable by providers at all of the following locations:
 - one retail pharmacy for each partner
 - one primary care facility for each partner
 - one emergency department for each partner

SAMHSA-Funded Integrations



S&I Initiative Background

- A collaborative community of participants from the public and private sectors who are focused on providing the tools, services and guidance to facilitate the functional exchange of health information.
- Creates a open and transparent process where healthcare stakeholders can focus on solving real-world interoperability challenges.
- Is a consensus-driven, coordinated, incremental standards process.
- Each S&I Initiative focuses on narrowly-defined, broadly applicable challenge, tackled through a rigorous development cycle, and provides input to Federal Advisory Committees for consideration.

S&I Initiative Pilots



WI PDMP



PMPi



PMP Gateway



October 2013
Connection

September 2014
Connection

VA Integration Pilot Background

- U.S. Department of Veterans Affairs is a partner in the eHealth Exchange
- VA wants to incorporate PDMP data into its EMR
- Identified the WI PDMP as a partner to pilot the process
 - VA submits data to the WI PDMP
 - WISHIN has connected to the eHealth Exchange

Public Health Portal

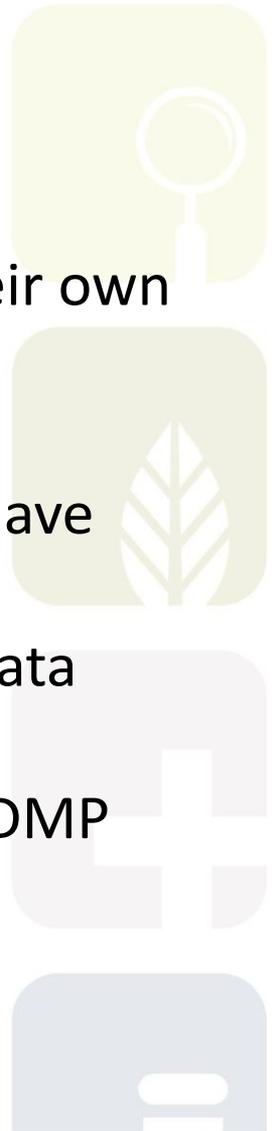


WI Project Scope

- Total Award: \$344,084
- Project Period: October 1, 2014 – March 31, 2016
- Goal: To give public health officials and other researchers access to de-identified data collected as part of the Prescription Drug Monitoring Program (PDMP).
- Proposed Project: Develop the **WI PDMP Public Health Portal**, a secure web-based database that authenticated users can query for specific de-identified information about the WI PDMP.

Public Health Portal

- Two types of User:
 - Public Health Officials and Researchers who have their own tools
 - Download flat file of PDMP data
 - Public Health Officials and Researchers who **do not** have their own tools
 - Interact with widgets and dashboards of PDMP data
- Obtain de-identified data by county, ZIP code or region
- Upload the final product based upon their research of PDMP data



CSB Goals

- CSB 2 – proactive scheduling (Ongoing)
- Maintain and seek-out general communications and educational efforts (Ongoing)
- Website review (Ongoing)
- SUA Review Process Update
- Electronic SUA Form
- Prescription Drug Abuse Efforts – PDMP/NGA/Legislation

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 5 August 2015 Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Controlled Substances Board			
4) Meeting Date: 14 August 2015	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Legislation and Rule Matters – Discussion and Consideration 1. CSB 2.39 Relating to Exclusion of Naloxegol 2. Phar 18 Relating to Data Submission to PDMP (Act 199) 3. Phar 18 Relating to Operation of Prescription Drug Monitoring Program 4. Scope for amending CSB 3 Relating to Special Use Authorization 5. Scope for amending Phar 18 Relating to Operation of Prescription Drug Monitoring Program (Act 55) 6. Update on CR 15-007 Relating to Hydrocodone Combination Products 7. Update on CR 15-008 Relating to Tramadol 8. Update on CR 15-009 Relating to Suvorexant 9. Update on Pending Legislation and Pending and Possible Rulemaking Projects	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both		8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:
10) Describe the issue and action that should be addressed: 			
11) Authorization			
<i>Sharon Henes</i>		<i>5 August 2015</i>	
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 RULE-MAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.39 relating to exclusion of naloxegol.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.20, Stats.

Statutory authority: ss. 961.11(2) and (4), Stats.

Explanation of agency authority:

961.11(2) After considering the factors enumerated in sub. (1m), the controlled substances board shall make findings with respect to them and promulgate a rule controlling the substance upon finding that the substance has a potential for abuse.

961.11(4) If 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:

Summary of, and comparison with, existing or proposed federal regulation:

On January 23, 2015, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing naloxegol from schedule II of the federal Controlled Substances Act. The scheduling action was effective January 23, 2015.

Plain language analysis:

The Controlled Substances Board did not receive an objection to excluding naloxegol as a schedule II under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on March 25, 2015 to similarly exclude naloxegol under chapter 961 effective April 1, 2015 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule amends 961.16(2)(a)(intro), Stats. which excludes naloxegol from schedule II.

Comparison with rules in adjacent states:

Illinois: Illinois does not exclude naloxegol from scheduling.

Iowa: Iowa does not exclude naloxegol from scheduling.

Michigan: Michigan does not exclude naloxegol from scheduling.

Minnesota: Minnesota has a bill to exclude naloxegol from scheduling.

Summary of factual data and analytical methodologies:

The methodology was to remove naloxegol from scheduling 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:

None.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

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 Tom.Engels@wisconsin.gov, or by calling (608) 266-8608.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at Sharon.Henes@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8935, or by email to Sharon.Henes@wisconsin.gov. Comments must be received on or before to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.39 is created to read:

CSB 2.39 Exclusion of naloxegol. Section 961.16(2)(a)(intro), Stats., is amended to read:
961.16(2)(a)(intro)Opium and substances derived from opium, and any salt, compound, derivative or preparation of opium or substances derived from opium. Apomorphine, dextrorphan, nalbuphine, butorphanol, nalmefene, naloxegol, naloxone and naltrexone and their respective salts and the isoquinoline alkaloids of opium and their respective salts are excluded from this paragraph. The following substances, and any of their salts, isomers and salts of isomers that are theoretically possible within the specific chemical designation, are included in this paragraph:

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)

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

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

PROPOSED ORDER

An order of the Controlled Substances Board to create Phar 18.04 (p)

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.385(2)(b), Stats.

Statutory authority: s. 961.385, Stats.

Explanation of agency authority: “The board shall establish by rule a program for monitoring the dispensing of monitored prescription drugs.” s. 961.385, Stats.

Related statute or rule: ch. Phar 18, Admin. Code

Plain language analysis:

This rule implements 2013 Act 199 requiring the name of the person, either from on the id presented or known by the pharmacist, to whom a drug is dispensed or delivered to be submitted to the prescription drug monitoring program.

Summary of, and comparison with, existing or proposed federal regulation: None

Comparison with rules in adjacent states:

Illinois: Illinois does not require the name of the person to whom a drug is dispensed or delivered to be submitted to the prescription drug monitoring program.

Iowa: Iowa does not require the name of the person to whom a drug is dispensed or delivered to be submitted to the prescription drug monitoring program.

Michigan: Michigan does not require the name of the person to whom a drug is dispensed or delivered to be submitted to the prescription drug monitoring program.

Minnesota: Minnesota does not require the name of the person to whom a drug is dispensed or delivered to be submitted to the prescription drug monitoring program.

Summary of factual data and analytical methodologies:

The methodology was to insert this requirement into the enumeration of required data to be submitted to the prescription drug monitoring program.

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

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

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 Eric.Esser@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at Sharon.Henes@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8366, or by email to Sharon.Henes@wisconsin.gov. Comments must be received on or before * to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 18.04 (p) is created to read:

Phar 18.04 (p) The name recorded under s. 450.11(1b)(bm), Stats.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on April 9, 2016.

(END OF TEXT OF RULE)

Sections 1, 2 and 3 repeal definitions not used.

Section 4 amends to make clear the temporary licenses are included in the practitioner definition.

Section 5 is repealed because tramadol is now a scheduled drug.

Sections 6, 7 and 8 are clean-up which was missed in the previous rule clean-up.

TEXT OF RULE

SECTION 1. Phar 18.02 (4) is repealed.

SECTION 2. Phar 18.02 (11r) is repealed

SECTION 3. Phar 18.02 (15g) is repealed.

SECTION 4. Phar 18.02 (17) is amended to read:

Phar 18.02 (17) “Practitioner” has the meaning given in s. ~~450.19 (1) (a)~~ 450.01(17), Stats, including persons granted temporary licenses to practice medicine and surgery, visiting professor licenses, camp physician or locum tenens license, or temporary educational permits to practice medicine and surgery, but does not include a veterinarian licensed under ch. 89.

SECTION 5. Phar 18.03 (3) is repealed.

SECTION 6. Phar 18.08 (1) (intro) is amended to read:

Phar 18.08 (1) The board shall exempt a dispenser from compiling and submitting dispensing data and from submitting a zero report as required under this chapter until the dispenser is required to renew ~~his or her~~ its license, or until the dispenser dispenses a monitored prescription drug, if the dispenser satisfies all of the following conditions:

SECTION 7. Phar 18.10 (1) (c) is amended to read:

Phar 18.10 (1) (c) The denial, suspension, revocation or other restriction or limitation imposed on the ~~dispenser’s pharmacist’s, dispenser pharmacist~~ delegated, practitioner’s, or practitioner delegate’s account pursuant to s. CSB 18.09 (3).

SECTION 8. Phar 18.10 (2) (a) is amended to read:

Phar 18.10 (2) (a) The ~~dispenser’s pharmacist’s, dispenser pharmacist~~ delegated’s, practitioner’s, or practitioner delegate’s name and address, including street address, city, state and ZIP code.

SECTION 9. 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)

STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.: CSB 3

Relating to: Controlled Substance Measurements for SUA's

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only): N/A

2. Detailed description of the objective of the proposed rule:

The proposed rule would require controlled substances to be measured in total weight in grams for solid controlled substances and in volume and concentration for liquid controlled substances.

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:

The proposed rule would require controlled substances to be measured in total weight in grams for solid controlled substances and in volume and concentration for liquid controlled substances for purposes of inventory list, records and application purposes. This would be a more accurate reflection of how these substances are measured. Currently the rule only indicates weight in grams regardless of the state of matter.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

961.335(8) The controlled substances board may promulgate rules relating to the granting of special use permits including, but not limited to, requirements for the keeping and disclosure of records other than those that may be withheld under sub. (7), submissions of protocols, filing of applications and suspension or revocation of permits.

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

50 hours

6. List with description of all entities that may be affected by the proposed rule:

Applicants and holders of special use authorization permits.

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:

None

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

None to minimal. It is not likely to have a significant economic impact on small businesses.

Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377

Department Head or Authorized Signature

Date Submitted

STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.: Phar 18

Relating to: Operation of PDMP

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only): N/A

2. Detailed description of the objective of the proposed rule:

The objective of the proposed rule is to make necessary changes to the rule resulting from 2015 Act 55 transferring the Prescription Drug Monitoring Program (PDMP) from the Pharmacy Examining Board to the Controlled Substance Board and to make minor clean-up changes.

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:

Due to the transfer of authority from the Pharmacy Examining Board to the Controlled Substance Board, there are several definitions and references which need clarification or updating. In addition, there is minor clean-up which is necessary to repeal unnecessary definitions, make language gender neutral, correction of the words "dispenser" and "dispenser delegate" which should be "pharmacist" or "pharmacist delegate" and the repeal of Phar 18.03(2) and (3) which are no longer necessary due to the recent scheduling of tramadol and 2013 Act 124.

The proposed changes do not change policy and are a clean-up to remove redundancy and create clarity.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

s. 961.385 (2) The board shall establish by rule a program for monitoring the dispensing of monitored prescription drugs.

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

75 hours

6. List with description of all entities that may be affected by the proposed rule:

Licensees who are authorized to prescribe and dispense controlled substances (physicians, advanced practice nurse prescribers, physician assistants, dentists, podiatrists, optometrists, pharmacists and pharmacies) and PDMP staff.

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:

There is no existing or proposed federal regulation that is intended to address the activities regulated by the proposed rule as it relates to PDMP.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

Minimal or no economic impact. It is not likely to have a significant economic impact on small businesses.

Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377

Authorized Signature

Date Submitted

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 8/14/15	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Kratom (Mitragynine) Scheduling - Discussion and Consideration – APPEARANCE	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Appearance by United Naturals representatives.			

Kratom Facts

What is Kratom?

Kratom is a botanical, also known as *Mitragyna speciosa* and is part of the coffee family. It's a natural botanical ingredient used in dietary supplements in low doses to safely provide a boost of energy and relief from minor muscle pain.

Where does it come from?

Kratom originates on trees grown in Southeast Asia.

What is it historically used for?

Kratom has a long history of safe use by consumers in Southeast Asia who use it for similar purposes as Americans drink coffee and use over-the-counter pain relievers.

Is Kratom legal in the United States?

Yes, with the exception of Indiana, Tennessee, Wisconsin and Vermont that have state laws classifying Kratom as a “Schedule I” controlled substance or banning the manufacturing, sale, financing or possession of Kratom.

What is the difference between natural, plant-based Kratom and synthetic Kratom?

Naturally occurring Kratom is a safe and pure product. Synthetic Kratom or adulterated Kratom—where synthetic compounds (or additional alkaloids) are added—can be dangerous. And worse, manufacturers selling such products, not natural plant-based Kratom, are marketing their products as “legal highs, not as lawful dietary supplements.”

How does Kratom affect the brain?

As a complex botanical product, Kratom contains many active compounds, some of which are believed to act on the brain. Other substances that act on the brain similarly are coffee and chocolate.

Should products with Kratom have warnings for some consumers?

Yes. Kratom products are not recommended for use by minors or for use by women who are pregnant or breastfeeding. Further, Kratom should not be used with alcohol due to possible adverse interactions.

Has the Food and Drug Administration (FDA) banned Kratom?

No. The FDA has not banned Kratom in the United States.

VivaZen Facts

What is VivaZen?

VivaZen is a liquid dietary supplement made from natural botanical ingredients sold in retail locations across the U.S. VivaZen provides consumers with a boost of energy and relief from minor muscle ache due to exercise-induced inflammation.

What is in VivaZen?

The primary ingredient that makes VivaZen so effective is natural Kratom, which originates on trees grown in Southeast Asia. Kratom is also known as *Mitragyna speciosa* and is part of the coffee family.

What makes VivaZen different from other Kratom products?

VivaZen is a liquid dietary supplement packaged in single-serve bottles (1.9 fluid ounces). VivaZen contains natural, plant-based Kratom.

Where is VivaZen made?

VivaZen is produced and bottled in Florida and California.

Does VivaZen work?

Absolutely. A typical VivaZen consumer can feel a noticeable effect in approximately 20 minutes after taking the dietary supplement.

Is VivaZen safe for everyone?

VivaZen is not recommended for use by minors, nor for use by women who are pregnant or breastfeeding.

How is VivaZen labeled?

VivaZen's label contains the following information and recommendations:

"Not intended for those under 18. Do not consume on an empty stomach. Do not consume if pregnant or breastfeeding, or if operating a motor vehicle, machinery, or if you have liver disorder, heart disease, high blood pressure, CNS disorder, or other medical condition, or are taking medication. Use responsibly. Never mix with alcohol or medication. Excessive use may cause nausea."

"Do not exceed 1 bottle in a 48 hour period. Do not consume for more than 4 weeks."

Does VivaZen support restrictions that protect consumer safety for Kratom based products?

VivaZen supports the safe use of plant-based botanical Kratom and restrictions that protect consumer safety, like prohibiting the sale to and use of Kratom products by minors.

Do you support efforts to restrict access to Kratom spiked with synthetic alkaloids?

At VivaZen, we firmly believe dietary supplements should only contain safe ingredients, like natural, plant-based Kratom. We support regulatory efforts to restrict products with Kratom spiked with synthetic alkaloids or other compounds.

Is VivaZen habit forming?

No. VivaZen is non-habit forming, when taken as directed. Kratom consumers may experience dependence, similarly to caffeine, if continuously consumed over long periods of time at high intake levels. That is why VivaZen is labeled as follows:

"Directions: Shake thoroughly to mix. The herbal extracts can be bitter, so take all in one shot or mix into iced tea, juice or soda. Consume entire bottle within 20 minutes for best results. Do not take on an empty stomach. First time users try half and wait 20 minutes. Do not exceed one bottle in a 48-hour period. Do not consume more than 4 consecutive weeks."

Myth vs. Fact: the Science and Safety of Kratom

Kratom (*Mitragyna speciosa*) is a natural botanical dietary supplement indigenous to Southeast Asia. Part of the coffee family, kratom has health and wellness properties and has been used for centuries, most commonly by manual laborers to combat fatigue and improve productivity. Natural botanical kratom is a safe product, used today by thousands of Americans. The scientific evidence supports the safety of kratom use. It's critical to consider the scientific facts, not agenda-driven hyperbole.

Myth: kratom is a dangerous and powerful, synthetic drug.

Fact: kratom is a natural botanical that produces mild effects on mood and function, like coffee and tea.

- Research shows many social and economic benefits of traditional kratom use[1][2]. However, in the United States kratom is heavily disparaged by sensationalist and uninformed media that inaccurately classify the natural botanical as a dangerous synthetic drug.
- What coffee is to Americans, kratom is to Southeast Asians. Kratom is used regularly by up to 70% of the male population in parts of the region. Comparatively, the National Coffee Association reports 61% of Americans drink coffee daily.
- Compared typical drugs of abuse, the effects of Kratom are relatively mild, and use, like that of coffee and tea, is more likely to support productive work and social relationships than to disrupt them.

Myth: kratom is highly addictive.

Fact: as with coffee, suddenly stopping kratom use may cause mild withdrawal symptoms.

- It's common knowledge that frequent and long-term coffee and tea drinkers often experience mild withdrawal effects, like headaches, if they abruptly quit[3].
- Similarly, frequent and long-term kratom users may experience mild withdrawal symptoms, described as benign and subsiding quickly, if they abruptly discontinue use[5].
- Further research reports, that like coffee and caffeine dependence, kratom dependence does not negatively affect social or economic livelihoods. In fact, evidence shows employment and marriage rates of kratom users in Southeast Asia are higher than among the general population of those regions[4][5].

Myth: kratom is unsafe.

Fact: significant data point to the safety of traditional kratom use.

- Animal toxicology studies have demonstrated kratom safety at remarkably high doses, and have not found respiratory depressant effects that so often lead to overdose deaths with opioids and sedatives[6].
- Despite global use of kratom in a wide variety of forms, deaths involving kratom use appear rare, and not definitively attributable to kratom.
- The sum of the scientific evidence examining traditional use demonstrates that the most common "adverse events" are relatively mild—upset stomach, occasional constipation and dizziness. Products like Tylenol have similar potential side effects.

Myth: kratom gives users a "high"-like buzz.

Fact: natural botanical kratom products are most commonly used for their wellness and fatigue-combating properties.

- Kratom can be prepared and used in a variety of ways—tea, powder, capsules, extracts and supplements—and can offer users relief from minor muscle ache, like that brought on by vigorous exercise, and a boost of energy.
- Unfortunately there are a few manufacturers that combine natural botanical kratom with synthetic substances, essentially spiking the product. This is concerning and should be addressed. However, it's important to recognize that nearly any natural substance, chamomile tea for example, can be spiked with synthetic substances, altering its properties and making it an unknown quantity.

When it comes to regulation, the unknown is often treated as the enemy. While kratom may be unknown to many in the United States, kratom's safety and quality of life enhancing benefits are well known and have been studied for decades. There are thousands, if not millions, of Americans who understand and safely experience the many wellness benefits of kratom.

1. Hassan, Z. et al. (2013). From Kratom to mitragynine and its derivatives: Physiological and behavioural effects related to use, abuse, and addiction, *Neuroscience and Biobehavioral Reviews* 37, 138-151.
2. Singh, D. et al. (2015). Social Functioning of Kratom (*Mitragyna speciosa*) Users in Malaysia, *Journal of Psychoactive Drugs* 47:2, 125-131.
3. Juliano, L.M. and Griffiths, R.R. (2004). A critical review of caffeine withdrawal: empirical validation of symptoms and signs, incidence, severity, and associated features, *Psychopharmacology* 176:1, 1-29.
4. Ahmad, K. and Aziz, Z. (2012). *Mitragyna speciosa* use in the northern states of Malaysia: A cross-sectional study, *Journal of Ethnopharmacology* 141, 446-450.
5. Singh, D. et al. (2014) Kratom (*Mitragyna speciosa*) dependence, withdrawal symptoms and craving in regular users, *Drug and Alcohol Dependence* 139, 132-7.
6. Raffa, Robert B. (2015). Short Overview of Mitragynines as contained in Kratom and Other Mitragynines: The Chemistry and Pharmacology of Opioids from a Non-Opium Source 2: 9-22.
7. Ramanathan, Surash et al. (2015). Toxicology of Mitragynine and Analogs as contained in Kratom and Other Mitragynines: The Chemistry and Pharmacology of Opioids from a Non-Opium Source 19: 281-296.

Wisconsin Controlled Substances Board Official Testimony
By Susan Ash
Director, American Kratom Association

My name is Susan Ash and I'm the founder and Director of the American Kratom Association (or AKA), a nonprofit formed by consumers for the purpose of protecting the right of all Americans to use the plant kratom (*Mitragyna Speciosa*) without undue influence from, or affiliation with, businesses that profit from it. We launched in February to represent and advocate for the approximately 2 million Americans who use kratom for medicinal purposes, and we greatly appreciate this opportunity to speak to you today.

As you know, we're here today because last year the state of Wisconsin classified the primary alkaloids in kratom, mitragynine and 7-OH (hydroxymitragynine), as Schedule I (Wis. Stat. § 961.14) and we—myself and fellow AKA members—believe that decision should be reversed.

The American Kratom Association has hundreds of dues-paying members, with more than 1,700 people in our advocacy group. We represent people from all walks of life, all over the U.S., many of whom are Wisconsin residents that are either afraid to speak about their kratom use for fear of being criminally prosecuted, or are simply at a loss for words over losing their rights to use what they consider a panacea for a variety of ailments, both large and small. We are everyday people: teachers, firefighters, environmentalists, and nurses, who've found kratom greatly improves our quality of life. We do not profit from kratom; we are consumers who rely on it. Though there are hundreds of stories I'd like you to hear, let me begin by sharing my own.

With a Master's Degree in Forestry, I was once a high-functioning professional directing non-profit environmental campaigns out West. My job required that I spend a lot of time in the forests I was working to protect. Around 2006 I became ill. Dozens of tests and doctors and incorrect diagnoses led to me being prescribed just about every drug imaginable (mostly narcotics) to treat my symptoms—mainly severe, unrelenting pain and fatigue. From morphine and all its derivatives to Xanax and Adderall, you name the controlled substance, and I can just about guarantee my doctors prescribed it. The Adderall was prescribed to treat the symptoms of fatigue from the morphine, the Xanax to treat an anxiety disorder worsened by the Adderall that gave me the energy to keep my job, and so on... Each additional drug was required to address the side effects of the previous prescription.

In 2008, in my late 30's, I was so ill I had to move back home to live with my parents. When my friends were out getting married and having children, I was reduced to a mostly home-bound existence under the care of my parents. In 2010, I finally got my diagnosis: late stage Lyme Disease. By that time it was so advanced I began giving myself daily intravenous antibiotics through a chest port and did this nearly a year. I never fully recovered and started receiving disability in 2011.

That's when I found kratom.

The narcotics were not enough to treat my pain, I was running out early and using them as an escape from what anyone would consider a miserable, hopeless existence. I began using kratom as a replacement for my pain medications when I ran out. In June of 2014, after a major surgical procedure, I started taking kratom daily and literally in just two weeks' time, I went from years of being mostly bedridden, only leaving my house to see doctors, to being able to travel to Wisconsin today from my home in Virginia to be here with you all. I have been taking kratom daily for over a year now, with a few intentional breaks.

Members of the AKA, like me, credit kratom for helping us return to jobs, families, and to LIFE. Our average member is 40 years old, professional and using kratom to manage many symptoms of chronic and often debilitating illness, not to feel intoxicated. Of the nearly 9,000 members of support groups I help moderate every day, I'd be challenged to find many who claim kratom makes them feel intoxicated, unlike the many drugs we've been prescribed by doctors, or alcohol, which is perfectly legal. In fact, most people feel more focused after consuming kratom. In the last four months, I have even been able, under a doctor's knowing supervision and approval, to go off four daily medications I was prescribed to treat the depression and anxiety that came from so many years of being chronically ill, and another four I was using on an as-needed basis to treat pain, fatigue and other symptoms of my Lyme Disease.

As you all know by now, kratom is an all-natural, herbal botanical in the coffee family. It does not belong in a category of synthetic drugs. Unlike what is printed in the DEA factsheet on kratom, it does have many traditional and current medicinal benefits and few, if any side effects. I, personally, have never experienced a single side effect in my year of daily kratom use, nor have I ever experienced withdrawal symptoms upon stopping it. I take breaks to combat any possible tolerance issues I've read about in the literature and about three months ago stopped using kratom "cold turkey" without so much as a runny nose, the most commonly cited withdrawal symptom from daily kratom use. Understanding the current debate on synthetics, kratom is neither dangerous nor synthetic in its natural form and it does not warrant being banned like synthetics, especially when dangerous new synthetic drugs like "flakka" are sweeping the U.S. in epidemic proportion. Ironically, flakka is currently *not on the DEA watch list* for drugs of concern; the DEA themselves have confirmed this.

According to one of the leading experts on kratom in the country, Dr. Christopher McCurdy of Ole Miss, unlike many dangerous pharmaceuticals, (even seemingly benign over-the-counter aspirin and acetaminophen products which cause over 16,500 deaths and send 78,000 Americans to the Emergency Room each year) kratom is not responsible for a single reported death. Kratom was not banned by the FDA, as media and legislators in states like Florida have claimed, but was placed on an FDA import-alert well over a year ago, because some companies were selling it by making claims it can treat disease. Since it's not yet FDA-approved, that's illegal; hence import alert 54-14 and a large seizure of \$5 million dollars' worth of kratom improperly marketed as curative of disease in CA last year. As an aside, it may be wise to let the actions of federal authorities investigating this plant take their course before passing laws banning its use.

Our members use kratom to relieve a variety of chronic illnesses and conditions, large and small, like pain, chronic fatigue, depression, anxiety, insomnia, ADHD, high blood pressure, MS,

fibromyalgia, Lyme Disease, to ease opiate withdrawals and to help manage addiction among many others. Thanks to kratom most of these people, including myself, no longer need or rely on dangerous (and often deadly) pharmaceuticals to function, and all report having better lives and healthier lifestyles. To say there is no medicinal use of this plant, when so many people are getting their lives back because of it, is a travesty to us. If there were no medical use, why would four patents have been filed on some of its alkaloids by pharmaceutical companies, the latest two just within the last two years?

Much of what you will find and hear in the medical community is based solely on opinion, not research. Research studies are desperately needed and funding to continue those already underway should be a priority. Many of the folks in this room are an integral part of that effort. Though I wasn't able to come armed with hundreds of pages of research studies—the results of the first peer-reviewed human clinical trial released in April showed no adverse effects from using kratom.

Further, what I did come armed with today is the history that led us here and a few hundred short testimonies from kratom consumers across the county to give you a glimpse of the diverse cross-section of people we represent.

Before I conclude, there are three important things I want leave you with:

First, the legislation that led kratom to be classified as Schedule I, had hundreds of compounds on the list. I would imagine most legislators didn't know what a majority of them were—but since they were presented, they were banned with little objection.

Since we've started working with legislators and regulators like yourselves, there have been eight states with similar bills on the table and through education and advocacy like this, have removed kratom and/or the primary alkaloids from their proposed bill language. Unfortunately for Wisconsinites, our advocacy efforts began shortly thereafter the bill passed here.

Second, the average kratom consumer looks like the average American. We're your neighbors, we're active in our communities, we're parents, we're professionals.

Last, but certainly not least, Kratom is a natural botanical and it's safe. I'm not interested in putting things that are dangerous in my body—that's part of what led me away from all the medications I was prescribed in the first place.

I, and all my members, thank you very much for your time and consideration today, and I look forward to answering any questions you may have.

Wisconsin Controlled Substances Board Official Testimony
By Kerry Biggs
Consumer from Milwaukee, Wisconsin

My name is Kerry Biggs, I'm a native of Milwaukee, Wisconsin, and currently reside in South Milwaukee. Thank you for the opportunity to speak with you today. I'd like to begin by sharing with you a bit about my life and my experience with kratom.

I am 35 years old, and the proud mother of 2 children: a three-year-old girl, and a ten-year-old boy. They are truly my heart and soul. My son has Goldenhar Syndrome—a congenital birth defect that involves deformities of the face, as well as a congenital heart defect and conductive hearing loss. I am also the primary caregiver for my disabled mother. I don't tell you this for your sympathy, I feel very blessed to be able to stay at home full-time to take care of my family. Rather, I tell you this because being a caretaker to others has become increasingly difficult as I'm struggling with my own medical issues.

Over the course of the last 5 to 6 years, I've been diagnosed with fibromyalgia, chronic fatigue, rheumatoid arthritis, IBS, diverticulosis and interstitial cystitis. In that time, I've been to countless doctors and specialists that have prescribed countless medications with countless side effects. While some medications would help with one diagnosis, it could exacerbate the symptoms of another. Most of the drugs my doctors prescribed left me feeling foggy—and foggy is not something I can afford to be as the primary caregiver for my mother and my kids.

When other peoples' lives and well-being rely on your own, you're willing to take matters into your own hands, or at least I was. I couldn't live another day in the fog my prescribed narcotics, antidepressants, and benzodiazepines they put me on. I knew there had to be a solution.

That's when I found kratom.

I'm very leery of things I put in my body, and found every piece of information I possibly could. After five months of research, I finally decided to try kratom and everything changed.

After taking kratom in powdered tea and capsule form, the change was almost instant. Instant relief from so many of the symptoms I suffered in silence from for so many years. I felt great, a feeling I hadn't had for too long. Within weeks of regular use, I had my life back, and I was in total disbelief! I no longer wanted, and better yet, or needed my pain medication. Over the course of the next few months I was able to go off all but one nerve medication. Antidepressants, narcotics, everything, I was off them all.

Kratom gave me the ability to care for my family properly again. I had a very low pain level, energy to spare and my mood was improved. With all of the medications, physical therapies, injections, tests and diagnoses, I finally had my answer. Kratom helps with symptoms of almost every single one of my diagnoses, which is why the need for kratom

in Wisconsin is so important. Frankly, it's necessary for my survival and quality of life, and is necessary for many others in my shoes. I strongly support a repeal on the ban in Wisconsin, where I choose and am happy to have chosen to live, work and raise my family.

Kratom is a plant that's been used safely and effectively for thousands of years. While I'm not a doctor, kratom has had a clear medicinal value for me, and I know that I'm not alone. It's restoring people's quality of life all over this great nation, and it's even helping to treat addiction.

Kratom gave me a new lease on life. That was until the ban. Now, I am back at square one, every day trying to do as much through the pain before my body literally gives out on me. Sadly, my story is not unique. It's like so many others that kratom has helped. Please allow those of us that prefer a natural, effective solution to have it. Please give this amazing plant a chance.

Thank you for your time and consideration today. I'm happy to answer any questions you may have.

Henningfield Biosketch

For State of Wisconsin Controlled Substances Board Review of Kratom

August 14, 2015

Jack E. Henningfield, Ph.D. is Vice President, Research, Health Policy, and Abuse Liability, at Pinney Associates, and Professor, Adjunct, Department of Psychiatry and Behavioral Sciences at The Johns Hopkins University School of Medicine. He was trained in abuse liability assessment in the 1970s in the Psychopharmacology Program at the University of Minnesota. He continued this work at Johns Hopkins beginning in 1978 where he has been on faculty to the present. He joined the National Institute on Drug Abuse from 1980 to 1996, as head of its Biology of Dependence and Abuse Potential Section, and the Clinical Pharmacology Laboratory, contributing to drug scheduling recommendations with the FDA and DEA. His research on drug abuse potential assessment and implications for drug scheduling span a broad range of drugs including opioids, sedatives, stimulants, cannabis, hallucinogenic drugs, and nicotine. He has published more than 400 articles, books and monographs on these topics and is a regular contributor to reports by the Surgeon General, Institute of Medicine, National Institutes of Health, and World Health Organization. He has received awards for these contributions from the World Health Organization, American Society of Addiction Medicine, United States Department of Health and Human Services, and other organizations. He participated with the Food and Drug Administration and other organizations in development of FDA's 2010 draft guidance, Assessment of Abuse of Drugs, and its 2015 final guidance: Abuse Deterrent Opioids – Evaluation and Labeling. At Pinney Associates, his focus is on abuse liability assessment, Controlled Substances Act 8-factor drug scheduling analyses, international drug scheduling, abuse deterrent formulation assessments, drug labeling, and risk management. See more at www.PinneyAssociates.com.

Revised: 27 July 2015

CURRICULUM VITAE

Jack E. Henningfield, Ph.D.

Personal:

Born: August 23, 1952, St. Paul, Minnesota
Married: Lucy L. Henningfield (Loyd)
Children: Travis L. Henningfield
Vincent B. Henningfield
Address: Pinney Associates, 4800 Montgomery Lane, Suite 400
Bethesda, Maryland, 20814
Home: 5504 Roland Avenue, Baltimore, Maryland, 21210
Email: jhenning@pinneyassociates.com

Education and Degrees:

1970-1974 - University of Minnesota, College of Liberal Arts
B.A., *summa cum laude*, Psychology, June, 1974.
1974-1977 - University of Minnesota, Graduate School
Ph.D., Experimental Psychology in Psychopharmacology Training
Program, June, 1977.

Post-Doctoral:

1977-1978 - Postdoctoral Research Fellow, National Council on Alcoholism,
at the University of Minnesota.
1978-1980 - Postdoctoral Research Associate, and Instructor, The Johns Hopkins
University School of Medicine and the Behavioral Pharmacology
Research Unit at Baltimore City Hospitals.
1980-1982 - Staff Fellow, NIDA Addiction Research Center, Baltimore, April.

Present Positions:

Pinney Associates, Bethesda, Maryland:
1996 (Sept. 1) - Vice President, Research, Health Policy, and Abuse Liability
www.pinneyassociates.com.
The Johns Hopkins University School of Medicine, Baltimore:
2002 (Nov. 26) - Professor (Adjunct), Behavioral Biology, Division of Behavioral
Biology, Department of Psychiatry and Behavioral Sciences.
The Johns Hopkins Bloomberg School of Public Health, Baltimore:
2003 – Institute for Global Tobacco Control, Affiliated Faculty
Food and Drug Administration, Center for Tobacco Products, Special Government
Employee 2013 to present.

Previous Positions:

1978 -1980 - Instructor of Behavioral Biology, Department of Psychiatry and Behavioral Sciences, The Johns Hopkins University School of Medicine.

1980 -1989 - Assistant Professor of Behavioral Biology, Department of Psychiatry and Behavioral Sciences, The Johns Hopkins University School of Medicine.

University of Maryland at Baltimore, School of Pharmacy:
1990 - 1993 Adjunct Professor, Program of Toxicology

1994 - 1995 - Adjunct Professor, Dept. of Psychology, Coppin State College.

Addiction Research Center - The Intramural Research Program of the National Institute on Drug Abuse, Baltimore:

1982 - August 31, 1996 - Pharmacologist, Addiction Research Center.

1984 -1985 - Acting Chief, Human Performance Laboratory, Addiction Research Center.

1984-1988 - Principal Investigator, U.S. Army Contract to Study the Effects of Drugs on Human Performance.

1989 - August 31, 1996 - Chief, Clinical Pharmacology Research Branch

1985 - August 31, 1996 - Chief, Biology of Dependence and Abuse Potential Assessment Section

1990 - August 31, 1996 - Coordinator, Minority Recruitment & Training Program, Addiction Research Center

The Johns Hopkins University School of Medicine, Baltimore:

1989 - 2002 - Associate Professor of Behavioral Biology, Part-time, Division of Behavioral Biology, Department of Psychiatry and Behavioral Sciences

The Johns Hopkins University School of Medicine, Baltimore:

2002 (Dec. 1) - National Program Director, Innovators Combating Substance Abuse Program, sponsored by the Robert Wood Johnson Foundation. Note: program funding ended in 2009; website and follow-up activities continue into 2011 www.InnovatorsAwards.org.

Food and Drug Administration, Center for Drug Evaluation and Research
2009 to ? – Special Government Employee (SGE)

Food and Drug Administration, Center for Tobacco Products, Special Government Employee (SGE). 2010 to 2013 – Tobacco Products Scientific Advisory Committee through 2011 and special projects

Awards and Professional Honors:

Summa cum laude graduate, June, 1974.

USPHS Predoctoral Fellow in Psychopharmacology, 1974-1977.

National Council on Alcoholism Postdoctoral Fellow, 1974-1978.

Fellow, American Psychological Association, Psychopharmacology and Substance Abuse Division (Division 28), 1986.

Vice President, International Study Group Investigating Drugs as Reinforcers, 1987.

Outstanding Service Award for work on the Report of the Surgeon General's Advisory Committee on the Health Consequences of Using Smokeless Tobacco. Presented by Surgeon General C. Everett Koop, M.D., Sc.D., April 27, 1987.

Outstanding Service Award for work as Scientific Editor on the Report of the Surgeon General on the Health Consequences of Smoking: Nicotine Addiction. Presented by Surgeon General C. Everett Koop, M.D., Sc.D., May 16, 1988.

Treasurer, American Psychological Association, Psychopharmacology and Substance Abuse Division (Division 28), 1989 to December 31, 1995.

Commemorative Medal from the World Health Organization, Tobacco or Health Programme. For "work having made a highly significant contribution to the understanding of the addictive nature of nicotine and tobacco, and your pioneering research on the treatment of nicotine addiction." Presented by the Deputy Secretary-General, WHO, Geneva, May 31, 1991.

Lincoln University Substance Abuse Prevention Conference. Distinguished Service Award "In recognition of excellence provided in opportunities for minority input and careers in research. Establishing a global network to better the health of mankind." Lincoln, PA, November 21, 1991.

Board of Directors, The College ("Committee" until 1991) on Problems of Drug Dependence, 1990-1994.

Fellow, American Psychological Association, Experimental Analysis of Behavior Division (Division, 25), 1992.

Selected for the Third Annual Donohoe Vascular Lecture, The George Washington University Medical Center, June 4, 1992, Washington, D.C.

Co-Chair, Tobacco Dependence Section, International Council on Alcohol and Addictions, 1993 - present. Lausanne, Switzerland.

Member, Ross Round Table on Critical Issues in Family Medicine: Substance Abuse Washington, D.C., October 13-14, 1993.

Charter Fellow and Membership Chair, Society for Research on Nicotine and Tobacco, 1994 - present.

NIDA Equal Employment Opportunity Award. National Institute on Drug Abuse, October, 1995.

NIDA Director's Award of Merit for activities as a member of NIDA's Minority Consortium and Equal Opportunity Office. National Institute on Drug Abuse, October, 1995.

American Society of Addiction Medicine, 1996 ASAM Annual Award "for expanding the frontiers of the field of addiction medicine and broadening our understanding of the addictive process, through research and innovation." Announced December, 1995. Presented April 20, 1996, in Atlanta.

NIDA Director's Award of Merit in recognition of exemplary achievements as a member of the Minority Recruitment and Training Program Staff. National Institute on Drug Abuse, September 25, 1996.

Alton Ochsner Award Relating Smoking and Health. For contributions that "have led to our understanding of the neuropharmacology of tobacco dependence demonstrating that tobacco consumption, through nicotine, is a true addiction and not merely a habit." Co-recipients of this award were Neal L. Benowitz, M.D., University of San Francisco, and Michael A.H. Russell, M.D., University of London. Presented at the Annual Convocation Ceremony of the American College of Chest Physicians, San Francisco, October 28, 1996.

US Department of Health and Human Services. Secretary's Award for Distinguished Service "for outstanding performance in the development of regulations to protect the nation's children from cigarette smoking." Presented by the Secretary of Health and Human Services, Dr. Donna E. Shalala and FDA Commissioner, Dr. David A. Kessler in Washington D.C. on February 28, 1997.

President, Society for Research on Nicotine and Tobacco, March 1998 - March 1999.

Annual Jellineck Award Lecture for the Yale School of Medicine, New Haven, November 7, 1997.

Joseph W. Cullen Award of the American Society of Preventive Oncology. Presented on March 6, 1998.

Innovators Combating Substance Abuse Award. September 2000 – August 2002. A nomination based award "that recognizes the Innovators contributions to the field [substance abuse] and that will allow the recipient to continue to seek innovative solutions to the nation's substance abuse problems." Sponsored by the Robert Wood Johnson Foundation and awarded July 2000 with two years funding.

Society for Research on Nicotine and Tobacco Ted Klein Commemorative Award. For the promotion of science in tobacco control. March 2001.

Senator Frank R. Lautenberg Annual Lecture in Public Health and Convocation Address. Public health the John Slade way. Convocation ceremony, class of 2002. University of Medicine and Dentistry of New Jersey, School of Public Health. Woodbridge Hilton, Iselin, NJ. May 20, 2002.

Fellow, American Psychological Association, General Psychology Division (1), 2002.

John Slade Award for outstanding contributions to public health and tobacco control through science-based policy and public health advocacy. Selected by Sir Richard Doll, Former Surgeon General C. Everett Koop, former FDA Commissioner David Kessler and Ms. Judith Wilkenfeld for the Society for Research on Nicotine and Tobacco. March 22, 2005.

Enduring Contributions in the Interest of Science Award, by The 7th Annual Dr. Lonnie E. Mitchell National HBCU Substance Abuse Conference. April 23, 2005.

Distinguished Visiting Scholar, Kansas University Medical Center. January 11, 2006

Choice Magazine. Addiction Treatment: Science and Policy for the 21st Century, by Henningfield, J.E., Santora, P.B, Dowell, M.L. and Bickel, W.K., was selected as one of the Outstanding Academic Titles of 2008.

Distinguished Service Award, College on Problems of Drug Dependence. Scottsdale, Arizona, June 13, 2010.

MED Associates Brady/Schuster Award, Psychopharmacology and Substance Abuse Division ("Division 28) of the American Psychological Association. San Diego, August 11, 2010.

British Medical Association, Medical Book and Patient Information Awards. Addiction and Art, by Santora, P.B, Dowell, M.L. and Henningfield, J.E., was distinguished as a "Highly Commended Book", September 14, 2011. Experts from BMA citation: *"Stunning and sometimes unsettling, this unique portfolio reveals addiction art as a powerful complement to addiction science. ...a pleasure to read and would be of great value a part of any addiction training course. ...a valuable tool for anyone involved in teaching addiction studies both as a source of 'addiction stories' and as a resource for focusing thought and discussion on the personal meaning of addiction."*

Presidential Citation Award, American Psychological Association. For research contributions to the science foundation for understanding tobacco as an addictive substance and contributions to the Food and Drug Administration, U.S. Congress, World Health Organization, and professional scientific organizations including APA, on the development of national and global policy and regulation to more effectively control tobacco addiction and disease. Presented at the Scientific Leadership Conference, by APA President, Melba Vazquez, Washington, D.C., October 23, 2011.

Spotlighters Theatre Award for Community Service. Presented to Jack and Lucy Henningfield for their dedication to community service and charitable fund-raising with a focus on the performing arts and addiction services. Spotlighters Theatre, Annual Gala, Baltimore, MD, October 26, 2014.

CEASE Tobacco Research Award. Presented at the First Annual Conference of the Morgan State University Communities Engaged in Advocating for a Smoke Free Environment (CEASE), Baltimore, MD, 21210, November 8, 2014.

Grant Review Activities:

NIDA, Behavioral and Clinical Drug Abuse, Initial Review Group (Ad Hoc, 1982 to 1990s, Member 1989-1992), and various Special Review Groups.

NHLBI, Ad Hoc Member, 1987 to early 1990s.

Veterans Administration, scientific review system.

Addiction Research Foundation (Toronto), scientific review system.

Robert Wood Johnson Foundation, science and policy grant review system.

Tobacco-Related Disease Research Program, University of California, Nicotine Dependence Study Section - Chair. April 1994; May 1997; April 1998, March 1999.

Minnesota Partnership for Action Against Tobacco, State Research Grants Program, Study section, 2000 to 2002, chair.

Policy Advisory Panel, American Legacy Foundation, Washington D.C., 2000 to present, member.

College of Reviewers, Canadian Research Chairs Program, 2001 to present, member.

Cancer Research, United Kingdom, 2002.

National Institutes of Health, Center for Scientific Review Special Emphasis Panel, March, 2007.

International Advisory Committees including the World Health Organization:

Barcelona Conference on the Clinical Testing of Drug Abuse Liability: Development of consensus and recommendations. Presentation: Drug self-administration methods in abuse liability evaluation. Barcelona, November, 1990

Canada's Expert Committee on Cigarette Modifications, Presenter and Discussant. Toronto, March 1-3, 1996; September 20-22, 1999.

United Kingdom Health Education Authority. Alternative Nicotine Delivery Systems. Presentation and Consultant. Presentation: Regulation of Nicotine in the U.S. London, November 25, 1996.

United States-Mexico Bi-National Commission Meeting: Smoking Prevention Core Group. Presenter and Consultant. Presentation: Understanding of Tobacco Addiction. Mexico City, March 3-5, 1997.

United Kingdom Anti-Smoking Tobacco Summit. Presenter and Consultant. Presentation: Consumer Protection Issues, London, July 14, 1997.

United Nations Council on Trade and Development (UNCTAD). Conference on Reduction of Tobacco Harm. Presenter and Consultant: (1) Nicotine Dependence as a Barrier for Reduction of Smoking-Related Mortality and (2) Discussion of Public Health Aspects of Widespread Use of Alternative Nicotine Delivery Systems (ANDS). Palais Des Nations, Geneva, September, 22-24, 1997.

European Commission Round Table on Smoking Control. Expert consultant. Plateau du Kirchberg, Luxembourg, Belgium, December 12, 1997.

Member, Expert Committee on Tobacco Research Issues. World Health Organization. Washington D.C., Campaign for Tobacco Free Kids, March 16, 1999.

Member, Expert Committee. Tobacco Intervention Policy for the World Health Organization. Mayo Medical Center, Rochester, MN, March 21-23, 1999.

Member, Committee on Treatment and Rehabilitation Models, Tobacco in Mexico Working meetings and seminars. Cocoyoc, Morelos, Mexico, August 26-28, 1999.

Member, Expert Panel on Nicotine and Nicotine Policy, European Institute of Oncology To provide guidance to European Commission regarding proposed Tobacco Directive. Milan, Italy, September 7 & 8, 1999.

Rapporteur and Expert, Conference on the Regulation of Tobacco Products, World Health Organization, European Region, Helsinki, Finland, October 18, 1999.

Participant, Conference on the Regulation of Tobacco Dependence Treatment Products World Health Organization. Helsinki, Finland, October 19, 1999.

Member, World Health Organization, Region of the Americas, Consultation Group, 1999 to 2000 (Report: Tobacco Control: Critical Review and Scope of Treatment in the Americas: Strategic Plan to Reduced Tobacco Caused Death and Disease in the Near Term, Pan American Organization, 2000).

Chair, Addiction Science Tract Planning Committee (1999-2000), 11th World Conference on Tobacco or Health Meeting held in Chicago, August 6-11, 2000.

Presenter and participant, Advancing Knowledge on Regulating Tobacco Products, World Health Organization. To provide guidance for WHO policy and the Tobacco Control Framework Convention. Oslo, Norway, February 9-11, 2000.

Expert, WHO Scientific Advisory Committee on Tobacco Product Regulation (SACTob). World Health Organization, Geneva. 2000 to 2004.

Expert, WHO Study Group on Tobacco Product Regulation (TobReg). World

Health Organization, Geneva. 2004 to 2014.

Nicotine Advisory Board, European Institute of Oncology, Milan, October 5&6, 2000

Rapporteur and Expert, Second World Health Organization European Meeting on the Regulation of Tobacco Dependence Treatment Products, Barcelona, Spain, October 13, 2000.

Advisor to International Agency for Research on Cancer (IARC), World Health Organization. Lyon, France. 2004 to present.

Report on Tobacco Control in India. Ministry of Health and Family Welfare, Government of India. New Delhi, India. 2004. Edited by K.S. Reddy and P.C. Gupta. Ministry of Health and Family Welfare, India; Centers for Disease Control and Prevention, United States; World Health Organization. Advisory role and reviewer.

Chairman, Expert Committee on Health and Smoking, Japan-U.S. Seminar for Treating Smokers. Tokyo Prince Hotel Park Tower, Tokyo, November 21, 2005.

Henningfield, J.E. Working Group Convened to Elaborate Guidelines for the Implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control. 2006 to present.

Other Advisory Committees and Governmental Consulting Activities:

Advisor to the Commissioner of the Food and Drug Administration, on behalf of the National Institute on Drug Abuse, on scientific issues regarding the introduction of a new nicotine delivery system, 1988.

Advisor to the Commissioner of the Food and Drug Administration, on behalf of the National Institute on Drug Abuse, on scientific issues regarding the addictiveness of nicotine delivery tobacco and pharmaceutical products, 1994-1996.

Technical advisor to American Lung Association on the pharmacologic basis and treatment of nicotine dependence, 1990.

Consultant and Ad Hoc Member Food and Drug Administration Subcommittee of the Drug Abuse Advisory Committee, 1990.

Alcohol/Substance Abuse Experts Working Group, American Psychological Association, 1991-1993.

Medications Development Guidelines Committee, Sub-Committee to the Drug Abuse Advisory Committee to the Food and Drug Administration, 1991.

Tobacco Advisory Board, George H. Gallup International Institute, 1991-1992.

Working Group. American Heart Association and the Coalition on Smoking or Health. Monterey, CA, January, 1993.

Working group on Nicotine Dependence. Tobacco Use: An American Crisis. American Medical Association. Washington, DC, January, 1993.

Consultant and Committee Member. Development of recommendations for coverage of treatment of substance abuse in potential health care reform legislation. National Center for Addiction and Substance Abuse (CASA), Columbia University, New York, March 6-7, 1993.

Committee Member. Consortium on Minority Concerns. National Institute on Drug Abuse. 1994 to 1996.

Committee Member. Robert Wood Johnson Foundation review of Etiology of Substance Abuse. Princeton, NJ, Jan. 13, 1995.

National Cancer Institute/National Institute of Dental Research Initiative on Spit Tobacco, 1995.

Chair, Study section for the Tobacco-Related Disease Research Program, University of California, San Francisco, California, May 22-23, 1997.

Senior Advisor. Robert Wood Johnson Foundation. Research Network on the Etiology of Tobacco Dependence (TERN), 1997 to 2004.

Centers for Disease Control and Prevention's Office on Smoking (CDC, OSH) and Health and Division of Adolescent and School Health (DASH): Tobacco Use Cessation Among Youth. Atlanta, September 15-16, 1997. Consultant and Discussant.

Member, The March Research Task Force. Behavioral Sciences Research Working Subcommittee, January 20, 1998.

Member, Ad Hoc Treatment Group, Center for the Advancement of Health. "Treating Tobacco Dependence in the U.S.," February 10, 1998.

Member, Youth Tobacco Prevention Initiative. Research Questions: A Transdisciplinary Approach to Youth Tobacco Use Prevention. Chair, Research Questions Committee. Robert Wood Johnson Foundation, October 16, 1998.

Founding Member, Committee on Tobacco Product Change, sponsored by the Campaign for Tobacco Free Kids. Washington, D.C., 1999 to present.

Member, Expert Committee. Tobacco Cessation Specialist and Program Certification and Training. Washington, DC, December 15, 1999.

Course Coordinator and Instructor (along with Joseph Gitchell), Cessation Programs at State and Local Levels. Tobacco use Prevention Training Institute, Centers for Disease Control and University of North Carolina. Denver, September 17-22, 2000 with Internet Provided Distance Learning supplemental course

Expert Panel Member, Robert Wood Johnson Foundation study to develop and test new tobacco use and treatment related measures on the Health Plan Employer Data and Information Set (HEDIS). 2000.

Member, Policy Advisory Panel, American Legacy Foundation, Washington D.C., 2000 to 2002.

Member, Expert Advisory Panel on Modified Tobacco Products, Massachusetts Department of Public Health, Tobacco Control Program, June 28, 2002 to 2004.

Expert Panelist and Program Committee, Conference on Abuse Liability Assessment of CNS Drugs. College on Problems of Drug Dependence. Bethesda, October 28-29, 2002.

Member, Initiative on the Study and Implementation of Systems (ISIS) – a National Cancer Institute Project to explore innovations in tobacco control science and public health efforts, 2003 to 2004.

Member, National Institute on Drug Abuse Clinical Trials Network, Data and Safety Monitoring Board, February, 2005 to 2008.

Discussion participant: First SAMHSA/CSAT Open Dialogue on the Issue of Non-Therapeutic Use of Prescription Medications. Rockville, Maryland, February 9, 2005.

Discussion participant: NIH State-of-the-Science Conference on Tobacco Use. Bethesda, Maryland, March 7-9, 2005.

Expert Panelist and Program Committee, Impact of Drug Formulation on Abuse Liability Safety and Regulatory Decisions Conference. College on Problems of Drug Dependence. Bethesda, April 19-20, 2005.

Recommendations work group leader: Risk Management Strategies. Impact of Drug Formulation on Abuse Liability Safety and Regulatory Decisions Conference. College on Problems of Drug Dependence. Bethesda, April 19-20, 2005.

Member, Interagency Committee on Smoking and Health, Centers for Disease Control and Prevention. July 1, 2005 to December 8, 2008.

Member, Scientific Advisory Board, Morgan State University, Center for the Study and Prevention of Drug Use. Baltimore, August 27, 2007.

Special Government Employee and Member, Tobacco Products Scientific Advisory Committee (TPSAC), Center for Tobacco Products, Food and Drug Administration, March, 2010 to 2011.

Centers of Biomedical Research Excellence (COBRE): Vermont Center on Behavior and Health, University of Vermont, Review Panel and Retreat, September 25, 2013, Member.

Consortium on Models Evaluating Tobacco (COMET), External Advisory Board Meeting.
University of Minnesota, Minneapolis, October 7, 2013, Chair.

Invited Testimony at Governmental Hearings and Committees

- On behalf of the National Institute on Drug Abuse on nicotine addiction. Before the United States House of Representatives, Committee on Energy and Commerce, Subcommittee on Health and the Environment. 100th Congress, Second Session. Hearing on the Health Consequences of Smoking: Nicotine Addiction. Washington, DC, July 29, 1988.
- On behalf of the National Institute on Drug Abuse, to support the Commissioner, Food and Drug Administration (Dr. David Kessler) on tobacco industry research on the assessment of abuse liability (“addictiveness”) of nicotine in animal models. Before the United States House of Representatives, Committee on Energy and Commerce, Subcommittee on Health and the Environment. 103rd Congress, Second Session. Hearing on the Health Effects of Smokeless Tobacco. Washington, DC, March 25, 1994.
- On behalf of the National Institute on Drug Abuse on the topic of addiction to smokeless Tobacco and the influence of pH on free nicotine. Before the United States House of Representatives, Committee on Energy and Commerce, Subcommittee on Health and the Environment. 103rd Congress, Second Session. Hearing on the Health Effects of Smokeless Tobacco. Washington, DC, November 29, 1994.
- Massachusetts Department of Public Health. Public Hearing on Proposed Regulations to be implement Massachusetts General Law Chapter 94, Section 307 C. Testified regarding labeling of Cigarettes and Smokeless Tobacco Products. Reports of Added Constituents and Nicotine Ratings. Boston, January 31, 1997.
- White House, Briefing for the Secretary, Department of Health and Human Services, and the President’s Advisory on Tobacco and Health Issues. Proposed National Tobacco Resolution. Reduction of Tobacco Caused Diseases, Washington, D.C. July 23, 1997.
- On the topic of tobacco addiction and treatment and request of Senator Jeffords to address the current state of the science, public health policy approaches, and FDA Regulation of tobacco. Before the United States Senate, Committee on Labor and Human Resources. February 24, 1998.
- Massachusetts Department of Public Health. Public Hearing on the Proposed Regulations to Declare Cigars Hazardous Substances Under the State Hazardous Substances Act, Boston, Massachusetts, May 21, 1998.
- United States Interagency Committee on Smoking and Health’s Subcommittee on Tobacco Cessation. Washington, D.C., October 24, 2002.
- United States Interagency Committee on Smoking and Health’s Subcommittee on Tobacco Cessation. Washington, D.C., February 11, 2003.
- United States House of Representatives, Committee on Government Reform. Hearing: Reduced exposure/reduced risk tobacco products: An examination of

the potential public health impact and regulatory challenges Washington, DC, June 3, 2003.

United States House of Representatives, Committee on Government Reform, Subcommittee on Criminal Justice, Drug Policy and Human Resources. Investigative hearing: To do no harm: Strategies for preventing prescription drug abuse. Testimony on behalf of Purdue Pharma. Winter Park, Florida, February 9, 2004. <http://fdsys.gpo.gov/fdsys/pkg/CHRG-108hhr10895555/html/CHRG-108hhr10895555.htm> (Accessed on 9 June 2009).

United States Senate, Health Education, Labor and Pension (Help) Committee. Invited testimony by Senator Edward M. Kennedy before the hearing on Senate Bill S.6.25: the Family Smoking Prevention and Tobacco Control Act, which would provide the Food and Drug Administration with effective authority to regulate tobacco products. Washington D.C., Dirksen Building, February 27, 2007.

United States House of Representatives, Committee on Government Reform, Subcommittee on Health. Invited by Chairman, Senator Henry A. Waxman to testify in the Hearing on H.R. 1108, Family Smoking and Prevention and Tobacco Control Act. Washington D.C., Rayburn House Office Building, Wednesday, October 3, 2007.

United States Senate, Commerce, Science and Transportation Committee, Chairman, Senator Daniel K. Inouye, Subcommittee on Consumer Affairs. Invited by Senator Frank R. Lautenberg to testify in the Hearing on the Accuracy of the FTC Tar and Nicotine Rating System. Washington D.C., Russell Senate Office Building, Tuesday, November 13, 2007.

Trial Testimony as Expert witness - NOTE THIS IS BEING UPDATED

Related to tobacco addiction for plaintiffs versus tobacco industry:

1986: Sean Marsee v. U.S. Tobacco, Oklahoma City.

1996 to present:

U.S. Department of Justice v. major cigarette manufacturers (Washington, D.C.).
For Attorney's Generals for the states of Mississippi, Florida, Texas, Connecticut, Missouri, Washington, Maryland, Massachusetts, Wisconsin, Oklahoma
For California Municipality (San Francisco area); Arch v. American Tobacco et al. (Pennsylvania); and Small & Fubini v. Lorillard Tobacco Co., et al. (New York); Little v. Brown and Williamson and R.J.Reynolds (South Carolina); McCune v. Philip Morris et al. (West Virginia); National Asbestos Workers Medical Fund et al. v. Philip Morris et al. Maryland); Grinnell v. American Tobacco/Brown and Williamson (Texas), Scott et al. v. American Tobacco et al. (Louisiana); West Virginia Consolidated Tobacco Litigation (Blankenship) v. Philip Morris et al.; Michael McMullin, et al. v. U.S. Smokeless Tobacco Co.; Haines; Christensen; West VA Consolidated; St. Louis v. Philip Morris et al.; Kelly Hill et al. v. U.S. Smokeless Tobacco Company; Evans, Executor v. Lorillard Tobacco Company et al.; Brown, California, Deposition, August, 2012, Tried May, 2013; St. Louis, Tried, February, 2011; Allen, Florida, McMannis, Florida; Whitney, Florida; Govea, Florida; Day, Florida

Florida Engle Progeny Litigation:

Townsend, Tried, 2010
Sulcer, Tried April, 2011
Evans, Tried, April, 2011
Gregory, Deposition, March 2011
Perry, Deposition, March 2011
Szymanski, Deposition April, 2011
Sulcer, Deposition, April, 2011
Allen, Trial, April, 2011, November 2014
Rivenburg, Deposition May-June?
Ramsey, Scheduled for Trial, May, 2011
Cox, Trial, December, 2011
Alexander, Deposition, July 2012
Rizutto, Deposition, July, 2012, Tried, August, 2013
Goviea, Deposition, August, 2013
Bishop/Ramsey, October, 2014

Other trial testimony:

Pharmacia Corp. vs. GlaxoSmithKline Consumer Healthcare, L.P. Civ. No. 02-5292 (MLC) (for GSKCH). Spring/summer, 2003.

Natural Answers, Inc. vs. SmithKlineBeecham (GlaxoSmithKline). U.S. District Court, Southern District of Florida, Case No. 04-22646-CIV UNGARO-BENAGES/BROWN. December, 2004 to January, 2005.

Co-Editor: Innovations, The Newsletter of the Innovators Combating Substance Abuse Awards Program of The Johns Hopkins University School of Medicine, supported by the Robert Wood Johnson Foundation; since 2004.

Past and present editorial boards:

Deputy Chair, Editorial Board, The Society for Research on Nicotine and Tobacco
Treatobacco.net
Associate Editor, Pharmacology and Addiction, for Tobacco Control
Editorial Board, Wellness Perspectives: Research, Theory and Practice.
Editorial Advisory Board, Clinical Advances in Smoking Cessation.
Editorial Board, Journal of Smoking-Related Disorders
Editorial Board, Prevention Science
World Health Organization/Society for Research on Nicotine and Tobacco Treatment Data
Base Project, Deputy Editor
Editorial Advisory Board, The Open Addiction Journal

Review and Editorial Activities:

Addiction
Alcohol Research and Health
Alcoholism: Clinical and Experimental Research
Addictive Behaviors
American Council on Science and Health
American Hospital Formulary Service Drug Information
American Journal of Public Health
Archives of General Psychiatry
Archives of Internal Medicine
Cancer Epidemiology Biomarkers and Prevention
Chest
CNS Drugs
Clinical Pharmacology and Therapeutics
Drug and Alcohol Dependence
Drug Evaluations
Experimental and Clinical Psychopharmacology
Growing up Tobacco Free, Institute of Medicine
Institute of Medicine Reports:
 Growing Up Tobacco Free, 1994
 Clearing the Smoke, 2001,
Nicotine Addiction in Children
Health Education Research
Health Psychology
Johns Hopkins University Press
Journal of Abnormal Psychology
Journal of Agricultural and Food Chemistry
Journal of the American Medical Association
Journal of Applied Social Psychology
Journal of Consulting and Clinical Psychology
Journal of Health Communication
Journal of Investigative Medicine

Journal of the National Cancer Institute
Journal of Pharmacology and Experimental Therapeutics
Journal of Preventive Medicine
Journal of Studies on Alcohol
Journal of Substance Abuse
Journal of Substance Abuse Treatment
Life Sciences
Mayo Clinic Proceedings
National Women's Health Resource Center Publications
New Zealand Ministry of Health Reports
 Chemical Factors Influencing the Addictiveness and Attractiveness of Cigarettes
 Novel Tobacco Products: Health Risk Implications for Smokers
Nicotine and Tobacco Research
Patient Care
Perceptual and Motor Skills
Pharmacology Biochemistry and Behavior
Physiology and Behavior
Preventive Medicine
Prevention Science
Proceedings of the Association of American Physicians
Psychological Bulletin
Psychological Reports
Psychopharmacology
Public Health Reports
Science
Smoking and Tobacco Control (National Cancer Institute)
The Medical Letter
Tobacco Control
Vascular Health and Risk Management

Membership in Professional Societies:

American Psychological Association -- Divisions 1, 3, 25, 28 and 38 (Fellow
 Div.25, 28)
International Study Group Investigating Drugs as Reinforcers
Behavioral Pharmacology Society
American Association for the Advancement of Science
Hastings Center Institute of Society, Ethics and the Life Sciences
The Johns Hopkins Medical and Surgical Association
College on Problems of Drug Dependence, Charter Fellow
American College of Neuropsychopharmacology
National Foundation for Mental Health, Founding Individual Member
Society for Research on Nicotine and Tobacco, Charter Member, President (1998-1999)
Drug Information Association (DIA)
Food and Drug Law Institute (FDLI)

Inventions and Patents

Two-stage transmucosal medicine delivery system for symptom relief, John Pinney et al. (number 6296.121). This patent was granted final approval in the U.S. in 2001, and is pending in several other countries.

Medicated chewing gum delivery system for nicotine, John Pinney et al. (number 6296.179). This patent was granted final approval in the U.S. in 2002, and is pending in several other countries.

Chewing gums, lozenges, candies, tablets, liquids, and sprays for the efficient delivery of medications and dietary supplements (6296.230). Under review by U.S. Patent Office

Extramural sponsorship

Current/Recent Research Collaborations

On most of the following research my role is as member of a scientific advisory group or an expert consultant on the research with the primary role being to contribute to the design, interpretation, and/or public health and policy implications of the research.

University of Minnesota, Department of Psychiatry. Various grants from 1971-1978 awarded to R.A. Meisch and T. Thompson supported my efforts as technician and/or collaborator on animal alcohol and other drug self administration research.

Johns Hopkins University School of Medicine, Department of Psychiatry and Behavioral Sciences. Various grants awarded to R. R. Griffiths, G.E. Bigelow, M.L. Stitzer et al., supported my collaborative research efforts that were mainly focused on tobacco self-administration in humans but also included establishing an oral baboon alcohol and sedative self administration preparation.

National Institute on Drug Abuse, Intramural Research Program (Addiction Research Center), supported my research from 1980 until I retired in 1996. I remain a research collaborator at NIDA but do not draw any salary or fees from NIDA.

Johns Hopkins University School of Medicine, Department of Psychiatry and Behavioral Sciences, Maxine Stitzer, P.I.: Abuse liability of flavored nicotine gum. Funded by Smith Kline Beecham Consumer Healthcare. Co-Investigator, 1997-1998

Johns Hopkins University School of Medicine, Department of Psychiatry and Behavioral Sciences, Maxine Stitzer, P.I.: Abuse liability of nicotine lozenge. Funded by Smith Kline Beecham Consumer Healthcare. Co-Investigator, 1999-2001.

Johns Hopkins University School of Hygiene and Public Health, Institute of Global Tobacco Control, Jonathan Samet, P.I.: Biomarkers of nicotine dependence in China. Funded by Smith Kline Beecham Consumer Healthcare. Co-Investigator, 1998-2000.

Transdisciplinary Tobacco Use Research Center (TTURC) Initiative Concept Mapping Planning Project. Funded by the National Cancer Institute, National Institute on Drug Abuse, and the Robert Wood Johnson Foundation. Advisor, 1999.

University of Wisconsin, Center for Tobacco Research and Intervention, Michael C. Fiore, Timothy B. Baker et al., P.I.s: Relapse: Linking Science and Practice, Transdisciplinary Tobacco Use Research Center (TTURC). Funded by the National Cancer Institute, National Institute on Drug Abuse, and the Robert Wood Johnson Foundation. Advisor, Expert Panel, 1999-2000.

Yale University School of Medicine, Stephanie O'Malley, P.I.: Transdisciplinary Tobacco Use Research Center, Naltrexone augmentation of nicotine patch therapy. Funded by National Cancer Institute, National Institute on Drug Abuse, Robert Wood Johnson Foundation. Scientific Advisory Board Member, 1999 to 2004.

Howard University, College of Medicine, Center for Drug Abuse Research, Ura Jean Oyemade Bailey, P.I.: Recruited research scientist advisory committee. Funded by the National Institute on Drug Abuse Advisory committee member 2000 to 2003.

Brown University Center for Behavioral and Preventive Medicine, David Abrams, P.I.: Transdisciplinary Tobacco Use Research Center (TTURC), Nicotine dependence and risk across generations. Funded by National Cancer Institute, National Institute on Drug Abuse, Robert Wood Johnson Foundation. Scientific Advisory Board Member, 2000 to 2004.

University of Minnesota, Dorothy Hatsukami, P.I.: Transdisciplinary Tobacco Use Research Center, Nicotine dependence and risk across generations. Funded by National Cancer Institute, National Institute on Drug Abuse, Robert Wood Johnson Foundation. Scientific Advisory Board Member, 2000 to 2004.

University of California, and San Francisco Veterans Administration Medical Center, Timothy Carmody, P.I.: Transdisciplinary Tobacco Use Research Center. Funded by National Cancer Institute, National Institute on Drug Abuse, Robert Wood Johnson Foundation. Scientific Advisory Board Member, 2000 to 2004.

Washington University School of Medicine, Theodore Reich, P.I.: Collaborative Genetic Study of Nicotine Dependence. Funded by the National Cancer Institute and the National Institute on Drug Abuse. Consultant, 2001 to 2005.

University of Nebraska, Medical Center, Jan Atwood, P.I.: Identifying Smoking Phenotypes. Funded by the National Cancer Institute. Consultant, 2001 to 2005.

Pinney Associates, Edward Cone, P.I.: Transmucosal oral diphenhydramine for rapid relief of nausea. Funded by National Institutes of Health, consultant, 2001.

Intramural Research Program, National Institute on Drug Abuse, Eric Moolchan, P.I.: Adolescent tobacco dependence treatment. Collaborator and advisor, 1999 to present.

Center for Health Promotion and Disease Prevention, Henry Ford Health System, Ronald Davis, P.I.: Analysis of Tobacco Depositions and Trial Testimony. Funded by the National Cancer Institute. Consultant, 2000 to 2005.

Team Member of Initiative on the Study and Implementation of Systems (ISIS) to Improve the Health Outcomes Related to Tobacco Use, 2001-2004. National Cancer Institute Sponsored resulting in NCI Tobacco Control Monograph Series No. 18, Greater than the Sum: Systems Thinking in Tobacco Control. US Department of Health and Human Services, 2007

University of Memphis, Kenneth D. Ward, P.I. International Tobacco and Health Research and Capacity Building Program. Funded by Fogarty International Center, National Institute on Drug Abuse, National Cancer Institute and Centers for Disease Control and Prevention. Advisory Board Member, 2002-2006.

Roswell Park Cancer Institute. Gary A. Giovino and K. Michael Cummings, CO-PIs.; Policy effects on cigarette design, emissions & behavior project. Funded by National Institutes of Health. Scientific Advisory Board Member and Consultant, to Health Research Inc., 2004 to 2008.

Center for the Evaluation of Nicotine in Cigarettes: An NIH supported multi center research project, in which I serve as an advisor and attend one meeting per year. Advisor since 2011.

EDUCATIONAL ACTIVITIES

Teaching

Since 1980, JEH has provided 1-3 lectures or seminars per year, upon request for courses addressing addiction related topics, primarily in the School of Medicine and School of Hygiene and Public Health, but also including special lectures, e.g., noontime series on Bayview Campus, for staff of the Center for Addiction and Pregnancy, and Cardiology Grand Rounds. Additional specific offerings are listed below.

Medical Student Elective: Nicotine Dependence and Public Policy, offered from 1980s to present.

Henningfield, J.E. Direct course and present papers entitled "Pharmacology of nicotine dependence" and "Smoking and other drug dependencies." Co-faculty: Gary Giovino, Centers for Disease Control, Office on Smoking and Health, and Mark Manley, National Cancer Institute. Held at the Annual 7th Medical Command/U.S. Army Europe Alcohol and Drug Abuse Prevention Control Program Conference, Bad Kissingen, Germany, June 14-15, 1990.

Johns Hopkins School of Public Health Institute for global tobacco control, 1999 to present, affiliated faculty.

Monthly evening seminar series on drug abuse related topics was initiated by JEH in 1982 and run until 1992. It included faculty and post doctoral fellows from Hopkins and several Baltimore-Washington areas schools, as well as visiting leaders in drug abuse research, treatment, and policy.

Alcohol, tobacco, illicit drugs, and public health, School of Hygiene and Public Health, James Anthony head instructor. JEH role was as tobacco lecturer during the initial 3 years that the course was developed and offered in the early 1990s.

Nicotine pharmacology and treatment of tobacco dependence. In annual course: Medical Pharmacology for Second Year Students. Johns Hopkins University School of Medicine. 1999 to present.

Johns Hopkins University, School of Public Health 18th Annual Summer Institute of Epidemiology and Biostatistics. Tobacco addiction: science, medicine and public health policy, 2001, lecturer.

Tobacco Control: National and International Approaches, School of Hygiene and Public Health, mid 1990s to present. JEH provides lecture on tobacco pharmacology, addiction, treatment and policy issues.

University of Maryland, Department of Psychiatry, Advanced Addictions Seminar. Present on the science, diagnosis and treatment of tobacco dependence. 1990s annual lectures.

Lectures are also provided on occasion for Baltimore area schools: Friends and Bryn Mawr.

Johns Hopkins University, Bloomberg School of Public Health 19th Annual Summer Institute of Epidemiology and Biostatistics. Tobacco addiction by design: implications for health policy, and harm reduction issues. June 24, 2002, lecturer.

History of tobacco control, nicotine addiction and public policy. Tobacco Control and the Law, University of Maryland Law School, Baltimore, Sept. 3, 2002, lecturer.

Johns Hopkins University Bloomberg School of Public Health. Distance Learning course be Internet: Tobacco addiction by design: implications for health policy, and harm reduction issues. 2005.

National Speakers Bureau Service for the American Psychological Association. 2007- present.

Johns Hopkins University Bloomberg School of Public Health. Distance Learning course be Internet: Tobacco addiction, recorded 2010.

Continuing Medical Education (CME)

JEH is regularly invited to provide lectures and organize mini-courses for continuing education credit for universities, professional organizations, and the Centers for Disease Control and Prevention. Over 100 of these have been approved for continuing education credit.

Mentoring and Advising

Except as noted, these advisees were supported by the Intramural Research Program (IRP) of the National Institute on Drug Abuse (NIDA) on the Johns Hopkins Bayview campus and their research was primarily done in the clinical research laboratories at the IRP and not with grant support.

Miyasato, Katsumasa, MD, NIDA, IRP, foreign medical fellow, 1981-1983. Presently Director, Nishihachiouji Hospital, Tokyo, Japan.

Frederick R. Snyder, BA, NIDA, IRP, pre-doctoral fellow, 1984-1986. Presently Project Director, NOVA, at NIDA, IRP, Bayview campus.

Caroline Cohen, PhD, NIDA, IRP, foreign fellow, 1989-1991. Presently Laboratory Chief, CNS department, Sanofi-Synthelabo Pharmaceuticals, Paris.

Carles Muntaner, MD, NIDA, IRP, foreign fellow, 1986-1989. Presently believed to be involved in public health research in Spain.

Samuel A. Klein, MD, NIDA, IRP, postdoctoral fellow and medical officer, 1987-1988. Presently believed to be in clinical practice in Detroit, MI.

Edward G. Singleton, PhD, NIDA, IRP, Senior Fellow, 1991-1994; JHU Behavioral Pharmacology Research Unit, Visiting Scientist. Presently Assistant Professor of Counseling Psychology, Co-Director of the University of Baltimore/Coppin State College Collaborative, and Director of B.A. in Psychology Division of Applied Psychology and Quantitative Methods, Yale Gordon College of Liberal Arts, University of Baltimore, MD.

Marilyn A. Huestis, PhD, NIDA, IRP, pre doctoral fellow and University of Maryland, Program of Toxicology, doctoral candidate, 1989-1992; JEH was a thesis advisor (“An Integrated Pharmacokinetic and Pharmacodynamic Study of Acute Marijuana Use”), PhD was awarded 1992. Presently Chief , NIDA, IRP, Baltimore, MD.

Amanda Jenkins, PhD, NIDA, IRP, pre doctoral fellow and University of Maryland, Program of Toxicology doctoral candidate, 1993-1995; JEH was a thesis advisor (“An Integrated Pharmacokinetic and Pharmacodynamic Study of Smoked Heroin and Cocaine in Humans”), PhD awarded 1995. Presently Chief Toxicologist, Cuyahoga County Coroner’s Office, Cleveland, OH.

Robert M. Keenan, MD, PhD, NIDA, IRP, senior staff fellow and medical officer, 1991-1993. Presently biomedical research consultant, and owner and staff physician of The Elite Center (weight control clinic), Baltimore, MD.

Mi Li, MD, NIDA, IRP, foreign fellow, 1992-1993. After an additional fellowship at the University of Arkansas (under Dr. Donald McMillan) Dr. Li is believed to have returned to China to take a lead role in addiction science research.

Leslie M. Schwandt (now Schuh), PhD, NIDA, IPR postdoctoral fellow; June 1993 – July 1995, NIDA, IRP. Presently, Scientific Communications Associate and Publication Coordinator Eli Lilly and Company, Indianapolis, IN.

Moolchan, Eric. T., M.D., Ph.D. Summer fellow from Howard University School of Medicine in the Minority and Recruitment Training Program at NIDA, IRP, 1995. Presently, Staff Physician and Director of the Teen Tobacco Addiction Treatment Research Center, NIDA, IRP, Baltimore, MD.

Bustamante, Ines. Doctoral student, doctoral examination committee. Johns Hopkins Bloomberg School of Public Health. Preventive interventions for tobacco use in Lima, Peru, December, 2003, to 2004.

Smith, Stephanie. Doctoral student. Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, 2002 to present.

Robert Wood Johnson Foundation Developing Leadership in Reducing Substance Abuse mentoring program

Garrett, Bridgette E., PhD. Behavioral Health Scientist at the Centers for Disease Control and Prevention, Office on Smoking and Health, Epidemiology Branch, Atlanta.

Asma, Samira, PhD. Health Scientist at the Centers for Disease Control and Prevention, Office on Smoking and Health, Epidemiology Branch, Atlanta.

Post doctoral fellows who joined my laboratory after completing fellowships in the Behavioral Pharmacology Research Unit (JHU Dept. Psychiatry and Behavioral Sciences)

Rosemary Nemeth-Coslett, PhD, NIDA, IRP, postdoctoral fellow, 1986-1987. Presently NIDA Extramural Division, tenured psychologist.

Phillip P. Woodson, PhD, NIDA, IRP, postdoctoral fellow, 1987-1989. Presently deceased having been primarily employed as a pharmaceutical industry, consultant since leaving NIDA.

Richard J. Lamb, Richard, PhD, NIDA, IRP, postdoctoral fellow, 1985-1988. Presently Associate Professor with Tenure, Departments of Psychiatry and Pharmacology, University of Texas Health Science Center at San Antonio, San Antonio, TX.

Stephen Higgins, PhD, NIDA, IRP, postdoctoral fellow, 1985-1986. Presently Professor, Departments of Psychiatry and Psychology, and Co-Director, Human Behavioral Pharmacology Laboratory.

Stephen J. Heishman, PhD, NIDA, IRP, postdoctoral fellow, 1988-1991. Presently Senior Investigator, Clinical Pharmacology and Therapeutics Branch, NIDA, IRP.

Fant, Reginald V. Ph.D., NIDA, IRP, postdoctoral fellow, 1985-1986. Presently Scientist, Pinney Associates, and head, Clinical Pharmacology Section, Bethesda, MD.

John D. Roache, , PhD, NIDA, IRP, postdoctoral fellow, 1985-1987. Presently Associate Professor (with tenure), Departments of Psychiatry and Pharmacology, and Associate Chief of the Division of Alcohol and Drug Addiction, University of Texas Health Science Center at San Antonio, San Antonio, TX.

Evans, Suzette M., Ph.D., NIDA, IRP, postdoctoral fellow, 1990-1992. Presently Associate Professor of Clinical Neuroscience and Research Scientist, Department of Psychiatry, College of Physicians and Surgeons of Columbia University, New York.

Thesis and doctoral examination committees

Marilyn A. Huestis, University of Maryland, Program of Toxicology, An Integrated Pharmacokinetic and Pharmacodynamic Study of Acute Marijuana Use, 1992, thesis advisor.

Amanda Jenkins, University of Maryland, Program of Toxicology, An Integrated Pharmacokinetic and Pharmacodynamic Study of Smoked Heroin and Cocaine in Humans, 1995, thesis advisor.

Stephanie Smith, Johns Hopkins Bloomberg School of Hygiene and Public Health doctoral candidate, 2005

Andrea C. Villanti, Johns Hopkins Bloomberg School of Hygiene and Public Health doctoral candidate, 2010

Art

Since advising the American Visionary Art Museum (AVAM) on aspects of its Mega Exhibit: High on Life: Transcending Addiction, shown in 2002-2003, in Baltimore, I have collaborated on the establishment of a program of drug addiction related art. See also Henningfield, J.E. Bridge to compassion: A scientist's perspective on addiction and art. Visions, magazine of the American Visionary Arts Museum, 8: 4-5, 2002. A computer disc providing a virtual tour of the AVAM exhibition was produced in collaboration with AVAM and Innovators Awards and is available at AVAM and from the Innovators Awards Program.

This has resulted in an addiction art program run by Innovators Awards of The Johns Hopkins University School of Medicine, and supported by the Robert Wood Johnson Foundation. The art program was developed in collaboration with Director and Founder of the American Visionary Art Museum and other organizations and individuals for the purpose of convening juried exhibitions with the theme dedicated to Putting a Human Face on Addiction and Recovery. The home of the series is the Annual National Dr. Lonnie E. Mitchell National Historically Black College and University Substance Abuse Conference each spring where the art has been shown and judged since 2004. Since 2005 many of the works from the spring showing have been shown in galleries developed for the Annual College on Problems of Drug Dependence Meeting. Works are used to produce a calendar each year since 2006, available at www.InnovatorsAwards.org. A book to be published by The Johns Hopkins University Press will be published in the fall of 2008 focused on addition related art.

Addiction Art related Exhibitions and Galleries: Art and Addiction: Putting a Human Face on Addiction and Recovery

2004: March 30 – April 2. Dr. Lonnie E. Mitchell National Historically Black College and University Substance Abuse Conference, Annual National Meeting, Baltimore, Maryland.

2005: March 20-22. Dr. Lonnie E. Mitchell National Historically Black College and University Substance Abuse Conference, Annual National Meeting, Baltimore, Maryland.

2005: June 18-23. College on Problems of Drug Dependence, Annual National Meeting, Orlando, Florida.

2005: October 26. A Gallery of Roadside Memorials from the Baltimore Washington Region. Presented at the Third Annual Symposium of the Innovators Awards Program: Alcohol screening, intervention and confidentiality requirements in trauma centers and emergency departments. Johns Hopkins University School of Medicine Baltimore, Maryland.

2006: April 5-9. Dr. Lonnie E. Mitchell National Historically Black College and University Substance Abuse Conference, Annual National Meeting, Washington DC.

2006: June 17-22. College on Problems of Drug Dependence, Annual National Meeting, Scottsdale, Arizona.

2007: March 29 – April 1. Dr. Lonnie E. Mitchell National Historically Black College and University Substance Abuse Conference, Annual National Meeting, Washington DC.

2007: June 16-21. College on Problems of Drug Dependence, Annual National Meeting, Quebec, Canada.

Dance Performance

Nutcracker Ballet, by the Baltimore Ballet Company, “Parent’s Dances” in opening Party Scene, 2003-2010. Grandfather Dance, 2011-2014.

Viennese Waltz Concert (Leslie Lamberson, partner) accompanying The Viennese New Year’s Celebration Concert by the Orchestra of St. Johns, Ellicott City, Maryland, January 16, 2011.

Tuerk House Dancing for Recovery Gala, Cha Cha (Shannon Thrasher, partner), Baltimore, Maryland, May 15, 2010.

Tuerk House Dancing for Recovery Gala, Waltz (Lucy Henningfield, partner), Baltimore, Maryland, June 3, 2011.

Tuerk House Dancing for Recovery Gala, Triple Argentine Tango (Lucy Henningfield and Shannon Thrasher, partners), Baltimore, Maryland, June 1, 2012.

Celebration of former Surgeon General C. Everett Koop’s 95th Birthday, Waltz (Lucy Henningfield, partner). Koshland Science Museum of the National Academy of Sciences, Washington, D.C., September 24, 2011.

Celebration of Vivian Henningfield’s 90th Birthday, Waltz (Lucy Henningfield, partner). Little Canada, Minnesota, October 15, 2011.

House of Cards, Episode 1, Presidential Inauguration Ballroom Gala Scene, filmed at Baltimore War Memorial Museum, April 2012, with Kevin Spacey (also dancing), David Fincher (director), Viennese Waltz (Lucy Henningfield, partner), released by Netflix, February 1, 2013.

Alzheimer’s Association Memory Ball, Bolero (Lucy Henningfield, partner). Baltimore, Maryland, April 12, 2014.

Baltimore Artscape, Bolero and Viennese Waltz (Lucy Henningfield, partner); Foxtrot, Quickstep, Swing, Waltz (Danette McCraw, partner), Baltimore, MD, July 18 and 20.

The Homestead Resort, Bolero (Lucy Henningfield, partner). Hot Springs, Virginia, September 5 and 6, 2014.

Bibliography

Books and Monographs:

48. Grabowski, J., Stitzer, M.L. and Henningfield, J.E. (eds.) Behavioral Intervention Techniques in Drug Abuse Treatment. NIDA Research Monograph, Vol. 46, Washington, D.C., U.S. Government Printing Office, 1984.
56. Henningfield, J.E. Nicotine: An Old-Fashioned Addiction, Vol. 1 in the Encyclopedia of Psychoactive Drugs Series, M. Cohen (ed.), New York: Chelsea House, 1985. Revised in 1986 with S.H. Snyder (new general editor) and B.L. Jacobs (associate editor).
59. Henningfield, J.E. and Ator, N.A. Barbiturates: Sleeping Potion or Intoxicant. In the Encyclopedia of Psychoactive Drugs Series, S.H. Snyder and B.L. Jacobs (eds.), New York: Chelsea House, 1986.
87. Pomerleau, O.F. Pomerleau, C.S. Fagerström, K.O. Henningfield, J.E. and Hughes, J.R., Nicotine Replacement: A Critical Evaluation. New York: Alan R. Liss, 1988.
134. Henningfield, J.E. and Stitzer, M.L. (eds.) New Developments in Nicotine Delivery Systems. New York: The Cortlandt Group Inc., 1991.
135. Brunton S.A. (primary author) and Henningfield, J.E. (ed.) Nicotine Addiction and Smoking Cessation (monograph). New York: Medical Information Services, 1991.
293. Kozlowski, L.T., Henningfield, J.E. and Brigham, J. Cigarettes, Nicotine, and Health – A Biobehavioral Approach. Sage Publications, Thousand Oaks, California, 2001.
368. Henningfield, J.E., Santora, P.B. Bickel, W.K. (Eds.) Addiction Treatment: Science and Policy for the Twenty-first Century. The Johns Hopkins University Press, Baltimore, 2007. *Selected by Choice Magazine as one of the Outstanding Academic Titles of 2008*.
375. Henningfield, J.E., London, E.D., Pogun, S. (Eds.). Nicotine Psychopharmacology. Handbook of Experimental Pharmacology 192. Springer-Verlag, Berlin Heidelberg, 2009.
390. Santora, Patricia B, Dowell, Margaret L. and Henningfield, J.E. Addiction and Art. The Johns Hopkins University Press, Baltimore, Maryland, 2010. *Placed in the “Highly Commended” category by the British Medical Association's 2011 Medical Book Awards*
392. Boyle, P., Gray, N., Henningfield, J., Seffrin, J. and Zatonski, W. (eds.) Tobacco and Public Health: Science and Policy, Second Edition. Oxford University Press, Oxford, 2010.
294. World Health Organization. Advancing Knowledge on Regulating Tobacco Products (monograph). Published by World Health Organization, Geneva, 2001 (JEH contributed material and assisted in preparation of the monograph).
- World Health Organization. Policy Recommendations for Smoking Cessation and Treatment of Tobacco Dependence. Vera da Costa e Silva, Editor. Geneva, 2003 (JEH contributed to the monograph).

World Health Organization, Scientific Advisory Committee on Tobacco Product Regulation (SACTob). Recommendation documents available in Arabic, Chinese, English, French, Russian and Spanish, at <http://www.who.int/tobacco/sactob/recommendations/en/>. Recommendation documents of the Committee with contributions and co-authorship by J.E. Henningfield:

Scientific Advisory Committee on Tobacco Product Regulation (SACTob)
Recommendation on Health Claims derived from ISO/FTC Method to Measure Cigarette Yield. World Health Organization, Geneva, Switzerland, 2002.

Scientific Advisory Committee on Tobacco Product Regulation (SACTob)
Recommendation on Nicotine and the Regulation in Tobacco and Non-Tobacco Products. World Health Organization, Geneva, Switzerland, 2003.

Scientific Advisory Committee on Tobacco Product Regulation (SACTob)
Recommendation on Tobacco Product Ingredients and Emissions (ISBN 92 4 159054 8). World Health Organization, Geneva, Switzerland, 2003.

Scientific Advisory Committee on Tobacco Product Regulation (SACTob) Statement of Principles Guiding the Evaluation of New or Modified Tobacco Products (92 4 159051 3). World Health Organization, Geneva, Switzerland, 2003.

Scientific Advisory Committee on Tobacco Product Regulation (SACTob)
Recommendation on Smokeless Tobacco Products (92 4 159055 6). World Health Organization, Geneva, Switzerland, 2004.

World Health Organization, Scientific Study Group on Tobacco Regulation (TobReg). Recommendation documents available in Arabic, Chinese, English, French, Russian and Spanish, at <http://www.who.int/tobacco/sactob/recommendations/en/>. Recommendation documents of the Committee with contributions and co-authorship by J.E. Henningfield:

Study Group on Tobacco Product Regulation (TobReg) Recommendation: Guiding Principles for the Development of Tobacco Product Research and Testing Capacity and Proposed Protocols for the Initiation of Tobacco Product Testing. World Health Organization, Geneva, Switzerland, 2004.

Advisory Note Waterpipe smoking: Health effects, research needs and recommended actions by regulators. World Health Organization, Geneva, Switzerland, 2005.

Study Group on Tobacco Product Regulation (TobReg) Report: Best Practices in Tobacco Control: Regulation of Tobacco Products in Canada. World Health Organization, Geneva, Switzerland, 2005.

World Health Organization and reviewed and approved through WHO process as an official WHO report. Tobacco: Deadly in Any Form or Disguise, World No Tobacco Day Monograph, WHO, Geneva, 2006 (J.E. Henningfield was lead author of report). (http://www.who.int/tobacco/communications/events/wntd/2006/Tfi_Rapport.pdf).

World Health Organization, The Scientific Basis of Tobacco Product Regulation; Report on the Scientific Basis of Tobacco Product Regulation: Report of a WHO Study Group (TobReg). WHO Technical Report Series, No. 945, Geneva, 2007. Co-Rapporteur/Chair: chapter

addressing “Contents and Design Features of Tobacco Products: Their Relationship to Dependence Potential and Consumer Appeal”

World Health Organization, The Scientific Basis of Tobacco Product Regulation; Report on the Scientific Basis of Tobacco Product Regulation: Second Report of a WHO Study Group (TobReg). WHO Technical Report Series, No. 951, Geneva, 2008. Co-Rapporteur/Chair: chapter addressing “Smokeless Tobacco Products: Health Effects, Implications for Harm Reduction and Research”

World Health Organization, The Scientific Basis of Tobacco Product Regulation; Report on the Scientific Basis of Tobacco Product Regulation: Third Report of a WHO Study Group (TobReg). WHO Technical Report Series, No. 955, Geneva, 2009. Co-Rapporteur/Chair: chapter addressing “TobReg Scientific Recommendation: Devices Intended for the Purpose of Nicotine Delivery to Respiratory System in Which Tobacco is not Necessary for their Operation”

World Health Organization, The Scientific Basis of Tobacco Product Regulation; Report on the Scientific Basis of Tobacco Product Regulation: Fourth Report of a WHO Study Group (TobReg). WHO Technical Report Series, No. 967, Geneva, 2012. Co-Rapporteur/Chair: chapter addressing “Recommendations on the Basis of a Regulatory Framework to Reduce the Dependence Potential of Tobacco Products”

Surgeon Generals and Other Reports to the US Congress and FDA Reports:

Contributor to Why People Smoke Cigarettes, a pamphlet by the U.S. Public Health Service, developed from testimony before the U.S. Congress by William Pollin, M.D., Director of the National Institute on Drug Abuse March 16, 1982. U.S. Dept. of Human Services, 1983.

Technical advisor to the National Institute on Drug Abuse in preparation of its First Triennial Report to the U.S. Congress on Drug Dependence Research. Co-author chapter on tobacco dependence with Thomas Burling, 1984.

Technical advisor on Advisory Committee to the U.S. Surgeon General on the health effects and dependence potential of smokeless tobacco, 1986-1987.

Second Triennial Report to the U.S. Congress on Drug Dependence Research, Nicotine dependence chapter, 1987.

The Health Consequences of Smoking—Nicotine Addiction: A Report of the Surgeon. Davis, R.M. (General Editor); Scientific Editors (alphabetic): Benowitz, N.L., Grunberg, N.E., Henningfield, J.E., Lando, H.A. Washington, D.C, U.S. Government Printing Office, 1988.

Third Triennial Report to the U.S. Congress on Drug Dependence Research, Nicotine dependence chapter, 1990.

Medications Development Guidelines Committee, Sub-Committee to the Drug Abuse Advisory Committee to the Food and Drug Administration, 1991.

Fourth Triennial Report to the U.S. Congress on Drug Dependence Research, Nicotine dependence chapter, 1994.

The Effect of Smoking and Smoking Withdrawal on Flight Performance: A 1994 Update, was completed by this task force in December, 1994)

Federal Liaison, Development of Smoking Cessation and Prevention Guideline Agency for Health Care Policy and Research, Office of the Forum for Quality and Effectiveness in Health Care. Development of the first Clinical Practice Guideline for Smoking Cessation in 1996. 1992-1996.

Contributing Editor and Contributing Author, A Report of the Surgeon General: How Tobacco Smoke Causes Disease. U.S. Department of Health and Human Services, 2010.

Food and Drug Administration. 21 CFR Part 801, et al. *Regulations restricting the sale and distribution of cigarettes and smokeless tobacco products to protect children and adolescents; proposed rule analysis regarding FDA's jurisdiction over nicotine-containing cigarettes and smokeless tobacco products; notice.* Federal Register, 60 (155), 41314-41792 (1995).
Liaison, as representative of the National Institute on Drug Abuse (NIDA) to the FDA to provide expertise pertaining to tobacco addiction science, diagnosis, treatment and prevention in the development of the Tobacco Regulation.

Food and Drug Administration. 21 CFR Part 801, et al. *Regulations restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents; final rule,* Federal Register, 61 (168), 44396-45318 (1996).
Liaison, as representative of the National Institute on Drug Abuse (NIDA) to the FDA to provide expertise pertaining to tobacco addiction science, diagnosis, treatment and prevention in the development of the Tobacco Regulation.

Participant, Nicotine and Product Regulation Subcommittee of the Congressional Advisory Committee on Tobacco Policy and Public Health (“Koop-Kessler” Committee), 1997.

Centers for Disease Control and Prevention’s Office on Smoking (CDC, OSH) and Health and Division of Adolescent and School Health (DASH): Tobacco Use Cessation Among Youth. Atlanta, September 15-16, 1997. Consultant and Discussant.

Centers for Disease Control and Prevention, Healthy People 2010 Tobacco Working Group

Contributor, Nicotine Addiction in Britain, A Report of the Tobacco Advisory Group of the Royal College of Physicians, London, 2000.

Health Canada Commissioned Report: Ferris Wayne G, Henningfield JE, “Tobacco Product Attractiveness as a Contributor to Tobacco Addiction and Disease.” 2008. Report to Health Canada, Ottawa, Canada

Food and Drug Administration Request for Comments: Comments on Draft Guidance for Industry – Assessment of Abuse Potential Drugs FDA Docket No. FDA–2012–N–1172.

Food and Drug Administration Request for Comments: Draft Guidance for Industry on Assessment of Abuse Potential of Drugs. Docket No. FDA-2010-D-0026 (at <http://www.regulations.gov/#!documentDetail;D=FDA-2010-D-0026-0006>) March 24, 2010.

Food and Drug Administration Request for Comments: Food and Drug Administration, Public Hearing and Request for Comments: Impact of Approved Drug Labeling on Chronic Opioid Therapy, Bethesda, Marriott Hotel, February 7-8, 2013 (written comments on PROP Petition to FDA Docket No. FDA-2012-N-1172).

Food and Drug Administration Request for Comments: Draft Guidance for Industry on Abuse-Deterrent Opioids – Evaluation and Labeling. Docket No. FDA-2013-D-0045: Draft Guidance for Industry on Abuse-Deterrent Opioids – Evaluation and Labeling (at <http://www.regulations.gov/#!documentDetail;D=FDA-2013-D-0045-0011>). March 14, 2013.

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Nicotine Dependency: The Behavioral Side (approx. 15 minutes). With Marc Manley, Ovide Pomerleau and others. Health Science Media, Inc., Atlanta, GA, 1991.

Feature Length Cinema Credit as interviewee: Addiction Incorporated. Produced and released by Acappella Pictures, Directed by Charles Evans, Jr. 2011.

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Selected Invited and Keynote Lectures

Henningfield, J.E. (with Thompson, T., Meisch, R.A.) Ethanol as a reinforcer: An operant analysis of ethanol dependence. Presented at the Second Bi-Annual International Symposium on Experimental Studies of Alcohol Intoxication and Withdrawal, International Council on Alcohol and Addictions. Manchester, England, June 26, 1974.

Henningfield, J.E. Keynote address: Laboratory models for the experimental analysis of human alcohol dependence. Presented at the annual meeting of the Minnesota Association for Behavior Analysis, St. Cloud, Minnesota, November 3, 1977.

Henningfield, J.E., Griffiths, R.R. and Jasinski, D.R. Human dependence on tobacco and opioids: Common factors. Presented at a NIDA-sponsored conference on the Behavioral Pharmacology of Human Drug Dependence, Belmont Center, Maryland, July, 1980.

Henningfield, J.E. and Jasinski, D.R. Pharmacological basis of tobacco use as a form of drug dependence. National Association on Drug Abuse Problems. New York, March, 1982.

Henningfield, J.E. Behavioral, physiologic and subjective effects of nicotine in humans. Visiting Scientist to Addiction Research Foundation, Ontario. Toronto, Canada, February, 1983.

Henningfield, J.E. Smoking addictions: Psychological aspects. Sixteenth Annual Taylor Manor Hospital Psychiatric Symposium: Double Diagnosis: Double Dilemma. The Polyaddictions" Alcoholism, Substance Abuse, Smoking, Gambling. Ellicott City, MD, April, 1984.

Henningfield, J.E. Tobacco use as an addictive process: Neurosciences and psychopharmacology. Presented at the Working Meeting on Tobacco Use as an Addictive Process, sponsored by NIDA and the John F. Kennedy School of Government of Harvard University, Boston, July, 1985.

Henningfield, J.E. Nicotine: Brain reward mechanisms. Berzelius Symposium VII: Brain Reward Systems and Abuse. The Swedish Society of Medicine. Gothenburg, Sweden, October 17-18, 1985.

Henningfield, J.E. Abuse liability and dependence potential of nicotine. International Symposium on Tobacco Smoking and Health: A Neurobiologic Approach. University of Kentucky, Tobacco and Health Research Institute. Lexington, KY, December, 1985.

Henningfield, J.E. Scientific basis for nicotine as an addictive substance. Tobacco Products Liability Conference. Northeastern University School of Law. Boston, MA, January 10-12, 1986.

Henningfield, J.E. Evidence that smokeless tobacco use may lead to dependence. Health Implications of Smokeless Tobacco Use, National Institutes of Health, Consensus Development Conference. National Institutes of Health, Bethesda, MD, January 13-15, 1986.

Henningfield, J.E. New fellows address entitled: Behavioral pharmacology of nicotine dependence. Presented at the Annual Convention of the American Psychological Association, Washington, DC, August, 1986.

Henningfield, J.E. Nicotine dependence: The interface between tobacco carcinogens and cancer. American Cancer Society's 29th Annual Science Writers' Seminar, San Diego Hilton, San Diego, CA, March 22-25, 1987.

Henningfield, J.E. Research issues in tobacco use cessation. 50th Anniversary Meeting of the National Cancer Institute: Smoking, Tobacco, and Cancer Program: Toward the Year 2000: The Role of Smoking Control in Cancer Reduction. National Institutes of Health, Bethesda, MD, April 27-29, 1987.

Henningfield, J.E. Biobehavioral models of addiction: Human models of abuse liability and dependence potential. Models of Addiction. Nashville, Indiana, May 30, 1987.

Henningfield, J.E. Tobacco dependence. Alaska Tobacco and Health Conference. Anchorage, Alaska, November 5, 1987.

Henningfield, J.E. Addiction potential of nicotine in cigarettes. Symposium on Smoking Cessation. A satellite meeting to the Sixth World Conference on Smoking and Health. Tokyo, Japan, November 7, 1987.

Henningfield, J.E. Pharmacokinetic and pharmacodynamic aspects of urine drug screening: Discussant/Reactor. Scientific Consensus Conference: Clinical Pharmacologic Implications of Urine Screening for Illicit Substances of Abuse. San Diego, California, March 7, 1988.

Henningfield, J.E. Laboratory studies relevant to assessing the impact of economic factors on the course and extent of drug dependence. Licit and Illicit Drug Policy: A Comparative Perspective. University of Michigan, School of Public Health, Ann Arbor, Michigan, March 10, 1988.

Henningfield, J.E. What every science teacher needs to know about addiction to nicotine. National Science Teachers Association, National Convention. St. Louis Missouri, April 9, 1988.

Henningfield, J.E. Nicotine Addiction (Keynote Address). American Lung Association. Augusta, Maine, June 16, 1988.

Henningfield, J.E. Behavioral and pharmacologic mechanisms of nicotine dependence. International Symposium on Nicotinic Receptors in the CNS -- Their Role in Synaptic Transmission. Uppsala, Sweden, June 19-21, 1988.

Henningfield, J.E. Pharmacology of nicotine: Nicotine as a drug of dependence. First National Conference on Nicotine Dependence of The American Medical Society on Alcoholism and other Drug Dependencies. Minneapolis, Minnesota, September 23, 1988.

Henningfield, J.E. Plenary Session: Nicotine among the addicting drugs: Implications for understanding, preventing and treating dependence and policy development. The Second Blaine House Conference on Alcohol and Other Drug Abuse, Prevention, Education, Treatment and Law Enforcement. Portland, Maine, November 29, 1988.

Henningfield, J.E. Discussant/Reactor. Smoking Cessation: Research and Development, Pharmacia. Rusthallargarden, Helsingborg, Sweden, February 27-28, 1989.

Henningfield, J.E. Is Cigarette Smoking an Addiction (symposium panelist (with S. Cummings, R.M. Davis, and N.A. Rigotti). American College of Physicians. San Francisco, April 14, 1989.

Henningfield, J.E. Nicotine dependence: Scientific basis for medications development. The Wilkerson Group Fourteenth Annual Business and Medicine Symposium. New York City, September 19-20, 1989.

Henningfield, J.E. Neuropharmacology of nicotine. The Second National Conference on Nicotine Dependence, American Medical Association on Alcoholism and Other Drug Dependencies. Chicago, September 21-24, 1989.

Henningfield, J.E. Smoking in the workplace: Fairness and self-preservation -- Nicotine addiction. National Safety Council. Chicago, October 31, 1989.

Henningfield, J.E. Tobacco as an addicting drug. Statehouse Day for a Tobacco-free Ohio. Columbus, Ohio, February 20, 1990.

Henningfield, J.E. Overview of the Addiction Research Center and scientific needs for increased minority involvement in research programs. Fourth Annual Coppin State College Substance Abuse Conference. Baltimore, April 27, 1990.

Henningfield, J.E. Direct course and present papers entitled "Pharmacology of nicotine dependence" and "Smoking and other drug dependencies", at the Annual 7th Medical Command/U.S. Army Europe Alcohol and Drug Abuse Prevention Control Program Conference, Bad Kissingen, Germany, June 14-15, 1990.

Henningfield, J.E. Tobacco addiction. Tobacco in the '90s. Palo Alto, California, July 25, 1990.

Henningfield, J.E. Food and tobacco self-administration: Common theoretical issues and research problems. Smoking and Body Weight Conference Workshop, Memphis State University and National Heart, Lung, and Blood Institute, Memphis, Tennessee, September 10-13, 1990.

Henningfield, J.E. Drug self-administration methods in abuse liability evaluation. Barcelona Conference on Clinical Abuse Liability Testing. Barcelona, Spain, November 5, 1990.

Henningfield, J.E. Pharmacologic basis and treatment of nicotine dependence. AMERSA (Association for Medical Education and Research in Substance Abuse). Rockville, Maryland, November 15, 1990.

Henningfield, J.E. The basis of nicotine dependency in cigarette smokers. Patient-Centered Smoking Cessation: An Office Based Model. Sponsored by The Heart of Harlem Cardiovascular Disease Program, Harlem Hospital, New York, November 18, 1990.

Henningfield, J.E. Introduction to Interventions for Cigarette Smoking, and Session Moderator. NIDA National Conference on Drug Abuse Research and Practice: An Alliance for the 21st Century. Washington, D.C., January 14, 1991. Abstract in National Institute on Drug Abuse, Conference Highlights, DHHS Pub. No. (ADM) 91-1818, pp. 35-36, 1991.

Henningfield, J.E., Cohen, C., and Heishman, S.J. Quantitative comparison of drug self-administration in animals and humans. International Symposium on Drug Dependence: From the Molecular to the Social Level, Mexican Secretariat of National Defense. Mexico City, January 22, 1991.

Henningfield, J.E. Successful Programs: The need for increased minority participation in basic research and clinical programs. Substance Abuse Prevention Conference, Lincoln University. Lincoln, Pennsylvania, February 21, 1991.

Henningfield, J. E. Clinical pharmacology of nicotine addiction. Presented as part of symposium entitled: "Pharmacology and therapeutics, dental hygiene education, and council of students - quit smoking curriculum workshop for dental educators. The American Association of Dental Schools, New Orleans, March 11, 1991.

Henningfield, J.E. Pharmacologic basis of smokeless tobacco dependence. First International Conference on Smokeless Tobacco: Tobacco and Health, Columbus, Ohio, April 12, 1991.

Henningfield, J.E. Contributions of behavioral pharmacology research to the understanding of nicotine dependence. "Distinguished Alumnus Lecture" Neuropharmacology Training Programs, University of Minnesota, Minneapolis, Minnesota, April 17, 1991.

American Lung Association - American Thoracic Society: 1991 International Conference: Anaheim, CA, May 12-15, 1991.

Henningfield, J.E. Clinical and Abuse Liability Testing Strategies. National Institute on Drug Dependence, Beijing Medical University, Beijing, China, September 10, 1991.

Henningfield, J.E. Program Chair, Introduction and Discussion: New Strategies in Smoking Cessation and Nicotine Dependence. The 43rd Annual Scientific Session of the American Academy of Family Physicians. Washington, D.C., September 24, 1991.

Henningfield, J.E. Program Chair, Introduction and Discussion: New Strategies in Smoking Cessation and Nicotine Dependence. The 57th Annual Scientific Assembly of the American College of Chest Physicians. San Francisco, November 4, 1991.

Henningfield, J.E. (With Former Surgeon General C. Everett Koop as Keynote Speaker) Program Chair, Introduction and Discussion: New Strategies in Smoking Cessation and Nicotine Dependence. The 64th Scientific Session of the American Heart Association. Anaheim, California, November 10, 1991.

Henningfield, J.E. Neuropharmacology of Nicotine. State of the Art in Addiction Medicine, California Society of Addiction Medicine. San Diego, November 22, 1991.

Henningfield, J.E. Pathophysiology of tobacco dependence. Smoking cessation Scientific Meeting. Hanbury Manor, Hartfordshire, England, March 2, 1992.

Henningfield, J.E. Smoking Cessation: Update 1992. Florida Osteopathic Medical Association, Annual Convention. Miami Beach, Florida, March 12, 1992.

Henningfield, J.E. Treatment of Smoking Addiction -- Agenda for the 90's. Reflections on the Bay, Miami, Florida, March 12, 1992.

Henningfield, J.E. Addressing Tobacco in Treatment of Other Addictions: Nicotine Pharmacology: The Physiological Basis for Nicotine Dependence and its Treatment. Princeton, New Jersey, March 19, 1992.

Henningfield, J.E. Pharmacotherapy for Nicotine Withdrawal. Symposium: New Pharmacologic Approaches for Detoxification. American Psychiatric Association, Washington, D.C., May 4, 1992.

Henningfield, J.E. New Strategies in Addiction Treatment -- Focus on Nicotine. American Lung Association Symposium on Nicotine Addiction : Agenda for the 1990's, Minneapolis, Minnesota, May 20, 1992.

Henningfield, J.E. (delivered by Lars Ramström) Tobacco dependence: Nature and mechanisms. 37th International Institute on the Prevention and Treatment of Alcoholism and 20th International Institute on the Prevention and Treatment of Drug Dependence. Sao Paulo, Brazil, August 6, 1993.

Henningfield, J.E. (delivered by Thomas Glynn) Tobacco: A drug of dependence. Cancer Prevention and Control, The Maria Sklodowska-Curie Memorial Cancer Center and the Institute of Oncology. Warsaw, Poland, September 7, 1993.

Henningfield, J.E. Nicotine Addiction: Focus on Adolescence. The Second Ross Roundtable on Critical Issues in Family Medicine. Washington, D.C., October 14, 1993.

Henningfield, J.E. Pathophysiology of Nicotine Addiction. The International Congress on Smoking Cessation. Glasgow, Scotland, March 5-8, 1994.

Henningfield, J.E. Pharmacological Determinants of Cigarette Smoking. International Symposium on Nicotine: The Effects of Nicotine on Biological Systems II. Satellite Symposium of the XII International Congress of Pharmacology. Montreal, Canada, July 21-24, 1994.

Henningfield, J.E. Pharmacological analysis of nicotine dosing issues. Food and Drug Administration. Drug Abuse Advisory Committee Meeting on the Abuse Liability of Nicotine Delivered via Cigarettes and Other Tobacco Products. Silver Spring, Maryland, August 2, 1994.

Henningfield, J.E. and Schuh, L.M. A critical review of the role of nicotine replacement therapy. The 9th World Conference on Tobacco and Health. Paris, October 10, 1994.

Henningfield, J.E. and Ramström, L.M. Tobacco dependence - scientific developments and implications for cessation practices. Satellite Symposia to the 9th World Conference on Tobacco and Health, organized by the Tobacco Dependence Section of the International Council on Alcohol and Addictions. Paris, October 9, 1994.

Henningfield, J.E. Regulating cigarette nicotine levels: Design and content (or Nicotine addiction facts to be reckoned with by regulation). American Society of Preventive Oncology. Houston, March 9, 1995.

Henningfield, J.E. Nicotine dependence: Commonalties and differences with other drug dependencies. 37th International Congress on Alcohol and Drug Dependence, Major Session. San Diego, August 21, 1995.

Henningfield, J.E. FDA's proposed tobacco regulation: Scientific underpinnings. Nicotine Dependence, Eighth Annual Conference sponsored by the American Society of Addiction Medicine. Toronto, October 14, 1995.

Henningfield, J.E. Biological and behavioral bases of tobacco addiction. National Institutes of Health, Health and Behavior Seminar Series. Bethesda, November 30, 1995.

Henningfield, J.E. Adverse behavioral effects of nicotine? Safety and Toxicity of Nicotine Symposium, Society for Research on Nicotine and Tobacco. Atlanta, December 5-6, 1995.

Henningfield J.E. Nicotine deliveries and consumer acceptability. Canada's Expert Committee on Cigarette Modification. Toronto, Canada, March 1-3, 1996.

Henningfield, J.E. Smokeless Tobacco: Bioavailability of nicotine and addiction research. Symposium on Smokeless/Spit Tobacco. Joint meeting of the International Association for Dental Research and the American Association for Dental Research. San Francisco, March 13, 1996.

Henningfield, J.E. Smoking cessation in the workplace: An analysis of cost recovery. Smoking: Its Impact on Employers' Benefit & Health Costs. Intramedical Health Services. Toronto, Canada, April 12, 1996.

Henningfield, J.E., Vocci, F. and Sachs, D.P.L. Smoking cessation medications. Symposium on Tobacco Addiction. The American Society of Clinical Oncology and the National Cancer Institute. Bethesda, NIH Campus, June 21, 1996.

Henningfield, J.E. Public health policy foundation: Up in smoke - Nicotine research travails. Keynote address for the National Institute on Drug Abuse Conference on Drug Abuse at the Annual Meeting of the American Psychological Association. Toronto, August 11, 1996.

Henningfield, J.E. Tobacco Addiction: Science, medicine, and public policy. National Institutes of Health, Medicine for the Public Special Lecture. Bethesda, October 15, 1996.

Henningfield, J.E. Chair and Organizer, Nicotine and smoking through the life cycle. American Society of Addiction Medicine's Ninth National Conference on Nicotine Dependence. Washington D.C., November 14-17, 1996.

World Health Organization (WHO). Workshop on Strengthening Collaboration on Global Tobacco Control. Presentation: Smoking Cessation and Nicotine Replacement Therapy. Atlanta, Georgia, November 6-9, 1996.

Henningfield, J.E. Addictive mechanisms of tobacco. INSP Meeting. Cuernavaca, Mexico, March 3, 1997.

Henningfield, J.E. Comparing the abuse potential of nicotine delivery systems. International Meeting: Alternative Nicotine Delivery Systems. Harm Reduction and Public Health. Toronto, March 21-23, 1997.

Henningfield, J.E. Grass Traveling Speaker Presentation: Nicotine Addiction: Pharmacology, Medicine and Regulatory Policy. Neuroscience Research Day. School of Medicine, University of Louisville. Kentucky, April 10, 1997.

Robert Wood Johnson Foundation Conference: Partnerships and New Paradigms for Tobacco Prevention Research. Presentation: Prevention of Nicotine Addiction: Neuropsychopharmacological Issues. Sundance, Utah, May 6-9, 1997.

Henningfield, J.E. Nicotine Addiction: A Global Perspective on Public Health and Policy Issues. SmithKline Beecham Consumer Healthcare, Global Meeting of Respiratory Tract and Smoking Cessation, London, April 21, 1997.

Henningfield, J.E. Physicians, Pharmacology and the Treatment of Nicotine Dependence: Pharmacodynamics of Nicotine. American Society of Clinical Oncology, Denver, May 17-18, 1997.

Henningfield, J.E. Tobacco Addiction: Pharmacological and Physiological Issues. National Institutes of Child Health and Human Development (NICHD). Conference on Smoking and Middle Childhood, Bethesda, Maryland, September 26, 1997.

Henningfield, J.E. Pathophysiology of Nicotine Dependence: Implications for the Regulation of Cigarettes and Treatment of Nicotine Dependence. Interactive Monoaminergic Basis of Brain Disease. Mojacar (Almeria), Spain, October 8-12, 1997.

Henningfield, J.E. Tobacco Addiction: Science, Medicine, and Public Health Policy. Given as the Annual Jellinek Lecture for the Yale School of Medicine, New Haven, Connecticut, November 7, 1997.

Henningfield, J.E., Shiffman, S., Burns, D.M. and Pinney, J.M. Exposure reduction therapy for cigarette smokers: principles of development and projected public health benefit. American College of Neuropsychopharmacology. Hilton Waikola, Kohala Coast, Big Island, Hawaii, December 10, 1997.

Henningfield, J.E. Smoking Cessation Methods. European Commission Round Table Discussion on Smoking Cessation, Luxembourg, December 12, 1997.

Henningfield, J.E. Nicotine Addiction: Basic Science, Medicine and Public Health. American Health Foundation Seminar, January 23, 1998.

Henningfield, J.E. Tobacco Addiction: Science, Medicine, and Public Health Policy. Joseph Cullen Memorial Lecture, American Society of Preventive Oncology. Bethesda, Maryland, March 4-6, 1998.

Henningfield, J.E. The Science of Tobacco: What is Known and What is Unknown. University of California, Irvine. The Tanner Lecture on Human Values. The Tobacco Wars: Risks and Rewards of a Major Challenge, California, March 9, 1998.

Henningfield, J.E. Tobacco Dependence Treatment Medication Regulation. The Food and Drug Law Institute. Conference on Tobacco Dependence: Innovative Regulatory Approaches to Reduce Death and Disease. (Conference Steering Committee and Presenter). Washington, D.C. April 8-9, 1998.

Henningfield, J.E. Pharmacology and Abuse Potential. American Cancer Society Conference. Cigar Smoking Health Risks: State-of-the-Science. (Conference Steering Committee and Presenter). Washington, D.C., June 15-16, 1998.

Henningfield, J.E. Smokeless Tobacco: Addiction, Treatment and Effects on Human Performance. National Athletic Trainer's Association. 49th Annual Meeting and Clinical Symposia. Baltimore, Maryland, June 17-20, 1998.

Henningfield, J.E. History of Pharmacology (Session Chair). Pharmacology of Nicotine (Presenter). National Institute on Drug Abuse and Centers for Disease Control and Prevention: Addicted to Nicotine Conference. Bethesda, Maryland, July 27-28, 1998

Henningfield, J.E. How Science has Promoted Tobacco Control in the US. Society for Research on Nicotine and Tobacco: First International Conference. Copenhagen, Denmark, August 22-23, 1998.

Henningfield, J.E. Tobacco: prevention, treatment and strategies: discussant. The International Council on Alcohol and Addictions (ICAA): The 42nd ICAA International Institute on the Prevention and Treatment of Dependencies. St. Julians, Malta, August 30-September 4, 1998.

Henningfield, J.E. An assessment of options for manipulating nicotine within the reduced harm context: maintain, increase, eliminate or reduce (pros and cons). Canada's Expert Committee on Cigarette Toxicity Reduction. Toronto, Canada, September 20-22, 1998.

Henningfield, J.E. Scientific Underpinnings of Tobacco Control in the US. National Cancer Research Center Conference Room. Tokyo, Japan, November 4, 1998.

Henningfield, J.E. The Science of Tobacco Dependence: The Changed Brain. Pan American Health Organization (PAHO): "Tobacco Control Critical Review and Scope of Treatment in the Americas". Washington, DC, January 10-14, 1999.

Henningfield, J.E. Current Issues in Nicotine Addiction. American Association of Health Plans: 2nd Annual Conference: Addressing Tobacco in Managed Care. San Diego, CA, January 31-February 2, 1999.

Henningfield, J.E. Options for the future regulation of tobacco products: Arguments for and against focussing on nicotine. II European, I Iberoamerican Conference on Tobacco or Health. Las Palmas De Gran Canaria, February 23-27, 1999.

Henningfield, J.E. (Chair and Discussant). Preventing Tobacco Use: Molecular to Marketplace Research Issues. Society for Research on Nicotine and Tobacco: 5th Annual Meeting. San Diego, CA, March 5-7, 1999.

Henningfield, J.E. Tobacco as the Primary Addicting Drug. Council to End Nicotine Addiction in Recovery: 5th Annual CENAR Conference. Holy Cross College. Worcester, MA, April 13, 1999.

Henningfield, J.E. Tobacco Policy: From Science and Medicine to Regulation and Public Health. The Lonnie E. Mitchell National HBCU Substance Abuse Conference. Baltimore, MD, April 28-May 1, 1999.

Henningfield, J.E. Pharmacological Basis for Nicotine replacement Therapy. Spanish Respiratory Society (SEPAR): Annual Congress. Barcelona, Spain, May 15-18, 1999.

Henningfield, J.E. Tobacco Dependence: Science, Medicine and Policy. National Institute of Respiratory Diseases: World No Tobacco Day Conference 1999. Mexico City, Mexico, May 31, 1999.

Henningfield, J.E. Tobacco Dependence Prevention and Treatment. Testimony to Joint meeting of the Pennsylvania Senate Public Health and Welfare and House Health and Human Services Committees, Harrisburg, Pennsylvania. June 22, 1999.

Henningfield, J.E. (with L. Ramstrom), Co Chair and presenter in Tobacco Dependence Section symposia on Cigarette Modification and Pharmacotherapy. International Council on Alcoholism and Addictions. Vienna, Austria, August 17, 1999.

Henningfield, J.E. Presentation on nicotine pharmacology and treatment to Committee on Treatment and Rehabilitation Models, Tobacco in Mexico working meetings and seminars. Cocoyoc, Morelos, Mexico, August 27, 1999.

Henningfield, J.E. Tobacco-delivered nicotine: How current regulatory loopholes allow the tobacco industry to maximize the addictive effects of nicotine. Expert Panel on Nicotine and Nicotine Policy, European Institute of Oncology, to provide guidance to European Commission regarding proposed Tobacco Directive. Milan, Italy, September 7 & 8, 1999.

Henningfield, J.E. (Chair); Workgroup: Ahluwalia, J., Boyd, R., Dalack, G., Burns, D., Etter, J.F., Fagerstrom, K.O., Kunze, M., Moolchan, E., Pillitteri, J., Richter, K.P., Schuh, L., Slade, J., Tyndale, R.F. and Windsor, R.A. Reduction of tobacco exposure. In SRNT Treatment Methodology Conference, Section I. Treatment Outcome Measures. Washington, DC, November 7 & 8, 1999.

Henningfield, J.E. and Henningfield, T.L. Tobacco and kids. Friends School third grade class. Baltimore, December 7, 1999.

Henningfield, J.E. Presentation and discussion of Conclusions from the Helsinki Conference on the Regulation of Tobacco Products (Oct. 1999). Advancing Knowledge on Regulating Tobacco Products, World Health Organization. To provide guidance for WHO policy and the Tobacco Control Framework Convention. Oslo, Norway, February 9, 2000.

Henningfield, J.E. Tobacco addiction and treatment. 40th Annual Conference on Cardiovascular Disease Epidemiology and Prevention. La Jolla, California, March 4, 2000.

Henningfield, J.E. Tobacco product regulation. The 31st Annual Medical Scientific Conference of the American Society of Addiction Medicine. Chicago, April 13-16, 2000.

Henningfield, J.E., Pillitteri, J. and Hughes, J.R. Clinical trial considerations. Committee to Assess the Science Base for Tobacco Harm Reduction, National Academy of Sciences, Institute of Medicine. Washington, D.C., April 25, 2000.

Henningfield, J.E. Pharmacotherapy for tobacco dependence. Mayo Clinic Nicotine Dependence Seminar. Rochester, Minnesota, May 8, 2000.

Henningfield, J.E. Tobacco addiction: science, medicine and public health policy. Johns Hopkins University 18th Annual Summer Institute of Epidemiology and Biostatistics. Baltimore July 6, 2000.

Henningfield, J.E. and Fant, R.V. How addictive is smokeless tobacco? Second International Conference on Smokeless/Spit Tobacco. Chicago, August 5, 2000.

Henningfield, J.E., Moderator, Nicotine Plenary Session, Nicotine: From Science to the Marketplace (with Alan Leshner, Greg Connolly and the simulated global launch of Clean Cut cigarette by Arnold Communications, and Jordon McGrath Case & Partners Euro RSCG, and Pinney Associates). 11th World Conference on Tobacco or Health. Chicago, August 8, 2000.

Henningfield, J.E. Why is quitting so hard? Understanding tobacco addiction, and Course Coordinator and Instructor (along with Joseph Gitchell), Cessation Programs at State and Local Levels. Tobacco Use Prevention Training Institute Centers for Disease Control and University of North Carolina. Denver, September 17-22, 2000, with Internet Provided Distance Learning supplemental course.

Henningfield, J.E. Presentations on Nicotine Bioavailability, Dose and measurement of nicotine, and Should we progressively reduce the dose? Meeting on Nicotine Policy, Nicotine Advisory Board. European Institute of Oncology, Milan, Italy, October 5 & 6, 2000.

Henningfield, J.E. Why do people keep starting to smoke? Why is quitting so hard? What can we do to help? Ministers of the European Parliament (Jules Maaten, Chris Davies, Robert Goodwill). Brussels, Belgium, October 11, 2000.

Henningfield, J.E. FTC/ISO cigarette testing: history and perspective. World Health Organization First meeting of the Scientific Advisory Committee on Tobacco Product Regulation (SACTob), World Health Organization, Geneva, October 12-13, 2000.

Henningfield, J.E. Conclusions of the Helsinki conference on regulation of tobacco dependence treatment products, and summary and conclusions of Barcelona meeting (as rapporteur). Second World Health Organization European Meeting on the Regulation of Tobacco Dependence Treatment Products, Barcelona, Spain, October 27, 2000.

Henningfield, J.E. Neuronal nicotine receptor research: Implications for understanding and treating tobacco addiction. Annual Investigator Meeting, Tobacco-Related Disease Research Program, San Diego, California, November 30, 2000.

Henningfield, J.E. Agonist treatments for substance abuse: nicotine. American College of Neuropsychopharmacology. San Juan, Puerto Rico, December 12, 2000.

Henningfield, J.E., Slade, J. Tobacco industry approaches to regulation efforts. World Health Organization, Second WHO Scientific Advisory Committee on Tobacco Product Regulation (SACTob). Atlanta, January 31-February 2, 2001.

Henningfield, J.E. (Reactor to FDA Controlled Substance Staff Presentation) Abuse liability and scheduling considerations in drug development. Temple University School of Pharmacy Conference on Creating New Knowledge: FDA and Industry in Dialogue. Philadelphia, April 3, 2001.

Henningfield, J.E. (Rapporteur) Regulation of nicotine replacement therapies. World Health Organization. Copenhagen, April 6, 2001.

Henningfield, J.E. (Panelist) Reducing tobacco harm, moderated by D.A. Kessler. Reducing Tobacco Harm Conference. Crystal City, VA, May 10-11, 2001.

Henningfield, J.E. (Plenary Speaker and Rapporteur) Current state of pharmacotherapy for nicotine addiction. National Cancer Institute – National Institute on Drug Abuse Working Group on Pharmacologic Approaches to Nicotine Addiction. Crystal City, VA, May 17-18, 2001.

Henningfield, J.E. (Presenter and Rapporteur) Mission of SACTob. World Health Organization, Third WHO Scientific Advisory Committee on Tobacco Product Regulation (SACTob). Penang, Malaysia, July 4-6, 2001.

Henningfield, J.E. (Meeting Co-Chair with B. Garrett, Presenter, and Conclusions) Ammonia treatment of cigarettes: implications for nicotine addiction. Panel on Ammonia and other facilitators of nicotine delivery. Centers for Disease Control and Prevention, Office on Smoking and Health, Atlanta, August 8, 2001.

Henningfield, J.E. Tobacco addiction science: Implications for prevention, treatment and health care policy. Interagency Committee on Smoking and Health. U.S. Department of Health and Human Services, Humphrey Building, Washington, D.C., August 14, 2001.

Henningfield, J.E. (Presenter and Course Co-Chair with C. Husten). Cessation programs at state and local levels. Centers for Disease Control and University of North Carolina Tobacco Use Prevention Training Institute, Portland, Oregon, August 19-24, 2001.

Henningfield, J.E. (Presenter and Co-Chair with C.A. Rose) Symposium: Behavioral Science Foundation of Tobacco Product Modification; Presentation: Regulatory challenges to reducing tobacco addiction: A behavioral science foundation. American Psychological Association, San Francisco, August 24, 2001.

Henningfield, J.E. (Presenter and Co-Chair with C.A. Rose) Symposium: Behavioral Science Foundation of Tobacco Product Modification; Presentation: Regulatory challenges to reducing tobacco addiction: A behavioral science foundation. American Psychological Association, San Francisco, August 24, 2001.

Henningfield, J.E. New developments in nicotine addiction: treatment implications. American Society of Addiction Medicine. Atlanta, September 16, 2001 (to be rescheduled due to September 11).

Henningfield, J.E. and Melihan-Cheinin, P. Global policy issues and research needs in tobacco control. Third Society for Research on Nicotine and Tobacco Conference: Advance on Neuroscience and Pharmacology of Nicotine, Paris, September 19, 2001 (presented by Dr. Cheinin due to September 11-caused flight cancellations).

Henningfield, J.E. (with William Corr, Executive Vice President, Campaign for Tobacco Free Kids). Science Policy Fellowship Orientation Symposium: The FDA and Tobacco Regulation: When Politics and Science Have Different Agendas; Present and discuss: Tobacco addiction

science foundation for public health policy : American Association for the Advancement of Science, Washington, D.C. September 19, 2001.

Henningfield, J.E., Rose, C.A. and Slade, J. New nicotine delivery devices – assessment using biomarkers (presentation); Panel Discussion (with D. Hatsukami, N. Benowitz, D. Hoffman, and M. Zeller): Biomarkers for the assessment of cigarettes. Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, University of Minnesota, Minneapolis, October 25-26, 2001.

Henningfield, J.E. Drug abuse prevention, treatment, training, and research opportunities. Dartmouth College and Koop Institute, November 8, 2001.

Henningfield, J.E. Tobacco use: epidemiology, pathogenesis and treatment. Ethics Research Consortium on Smoking and Genetics. Georgetown Public Policy Institute, Georgetown University. Washington, D.C., November 30, 2001.

Henningfield, J.E. (Rapporteur) Present summary and conclusions. Regulation of tobacco products and regulation of treatment products. World Health Organization. Prague, Czech Republic, December 14, 2001.

Henningfield, J.E., The use, risks and benefits of tobacco industry presentations and data. Modification of the reinforcing effects of cigarettes by chemical manipulations such as ammonia and menthol treatment. Scientific Advisory Committee on Tobacco Product Regulation, World Health Organization, Oslo, Norway, Feb. 4-6, 2002.

Henningfield, J.E. Reflections on John Slade: images, feelings, thoughts, future. Annual meeting of the Robert Wood Johnson Foundation Developing Leadership in Substance Abuse and Innovators Combating Substance Abuse Program, New Orleans, March 13-15, 2002.

Henningfield, J.E. and Garrett, B.E. Racial differences in smoking behavior: The current debate regarding menthol cigarettes. Ethical Issues in Smoking and Genetics, Institute for Health Care Research and Policy, Georgetown University, Washington, D.C., March 19, 2002.

Henningfield, J.E. Presenter: Addiction concepts and potential mechanisms of altering addiction prevalence, and moderator: The biochemistry and physiologic impact of menthol. The First Conference on Menthol Cigarettes: Setting the Research Agenda, Centers for Disease Control and Prevention, Atlanta, March 2, 2002.

Henningfield, J.E. The current state of epidemiological data on trends in prescription drug abuse. The Dr. Lonnie E. Mitchell National HBCU Substance Abuse Conference. Baltimore, April 4, 2002.

Henningfield, J.E. New nicotine delivery systems: harm reduction or public health menace – scientific, public health and regulatory challenges. Tobacco Topic Luncheon Meeting. U.S. Department of Health and Human Services, Humphrey Building, Washington D.C., April 10, 2002.

Henningfield, J.E. Safer cigarettes: science, policy, and regulatory challenges. Transdisciplinary Tobacco Use Research Center, special lecture series. University of California, Irvine, April 11, 2002.

Henningfield, J.E. Senator Frank R. Lautenberg Annual Lecture in Public Health and Convocation Address. Public health the John Slade way. Convocation ceremony, class of 2002. University of Medicine and Dentistry of New Jersey, School of Public Health. Woodbridge Hilton, Iselin, NJ. May 20, 2002.

Johanson, C.E. and Henningfield, J.E. (co-chair and introduction) Human drug abuse liability assessment: research and drug development challenges. Workshop at the College on Problems of Drug Dependence, Quebec City, Canada, June 10, 2002.

Henningfield, J.E. Pharmacotherapy and behavioral therapies to treat tobacco dependence. Global Policy for Smoking Cessation, World Health Organization, and Ministry of Health of the Russian Federation. Moscow, June 14-15, 2002.

Henningfield, J.E. Key note address: The future of treatment. Global University on Tobacco Control, sponsored by GlaxoSmithKline. Warsaw, Poland, June 19, 2002.

McNeil, A. and Henningfield, J.E. (invited co-chairs) Co-regulation of tobacco products and treatment products – roundtable symposium. Third European Conference on Tobacco or Health, World Health Organization Collaborating Center. Warsaw, Poland, June 20, 2002.

Henningfield, J.E., Wilkenfeld, J. and Zeller, M. U.S. case study and history: FDA attempt to co-regulate tobacco and treatment. In: Co-regulation of tobacco products and treatment products – roundtable symposium. Third European Conference on Tobacco or Health, World Health Organization Collaborating Center. Warsaw, Poland, June 20, 2002.

Foreit, J., Henningfield, J.E. and Rose, C.A. Availability and marketing of novel nicotine products in the U.S. in the absence of regulation. In: Co-regulation of tobacco products and treatment products – roundtable symposium. Third European Conference on Tobacco or Health, World Health Organization Collaborating Center. Warsaw, Poland, June 20, 2002.

Henningfield, J.E. Reducing tobacco-caused disease: scientific and regulatory challenges. In: Health consequences of smoking and reducing its risk, co-chaired by Martin Jarvis, Richard Peto and Vesna Kerstin-Petric. Third European Conference on Tobacco or Health, World Health Organization Collaborating Center. Warsaw, Poland, June 20, 2002.

Henningfield, J.E. Johns Hopkins University 19th Annual Summer Institute of Epidemiology and Biostatistics. Tobacco addiction by design: implications for health policy, and harm reduction issues. June 24, 2002.

Henningfield, J.E., Moolchan, E.T. and Zeller, M. Reducing addiction and other tobacco-caused diseases in the young: biological, public health and regulatory issues. Innovations in Youth Tobacco Control, University of Michigan Tobacco Research Network, The Robert Wood Johnson Foundation, The Ted Klein Youth Tobacco Research Project. Santa Fe, New Mexico, July 8-11, 2002.

Henningfield, J.E. History of tobacco control, nicotine addiction and public policy. Tobacco Control and the Law, University of Maryland Law School, Baltimore, Sept. 3, 2002.

Henningfield, J.E. Dynamics of nicotine addiction. Third International Conference on Smokeless Tobacco: Advancing Science and Protecting Public Health. Stockholm, Sept. 22-25, 2002.

Connolly, G. and Henningfield, J.E. New smokeless tobacco products. Third International Conference on Smokeless Tobacco: Advancing Science and Protecting Public Health. Stockholm, Sept. 22-25, 2002.

Henningfield, J.E. Tobacco product regulation. Plenary Session: Addressing the tobacco epidemic in the 21st century: major challenges and future horizons. World Forum on Drugs. Montreal, Sept. 25, 2002.

Henningfield, J.E. Bridge to compassion: A scientist's perspective on addiction and art. Opening press conference to the American Visionary Art Museum's Exhibition: High on Life: Transcending Addiction. Baltimore, October 20, 2002.

Henningfield, J.E. Harm reduction: Lessons learned from past experiences, current environment, and future directions. National Conference on Tobacco or Health. San Francisco, November 20, 2002.

Henningfield, J.E. Science foundation for tobacco harm reduction. University of Minnesota Transdisciplinary Tobacco Use Research Center. Minneapolis, December 6, 2002.

Henningfield, J., Di Marino, M., Rohay, J., Clayton, R., Jones, S., Wilcox, P., Ousey, G., Hunt, S. and Reeder, K. Prescription Drug Abuse Patterns in Youth and Adults: Implications for Prevention Programming. Presented at the Annual Meeting of the American College of Neuropsychopharmacology. San Juan, December 11, 2002.

Henningfield, J.E. Chair Drug Addiction in America: A 21st Century Agenda for Science, Policy and Innovation. Innovators Awards Program. National Press Club, Washington, D.C., February 12, 2003.

Henningfield, J.E. Introduction to C.E. Koop, Keynote Address: Drug Addiction in America: A 21st Century Agenda for Science, Policy and Innovation. Innovators Awards Program. National Press Club, Washington, D.C., February 12, 2003.

Henningfield, J.E. Moderate Panel and summarize state of science and policy; Innovations in the Prevention and Treatment of Addiction: Challenges for Research and Policy Development. Panelists: J.V. Brady, C. DiClemente, S. Headen, R. Hingson and H. Jones. Innovators Awards Program. National Press Club, Washington, D.C., February 12, 2003.

Henningfield, J.E., Moolchan, E.T. and Zeller, M. (Presented by M. Zeller). Regulatory strategies to reduce tobacco addiction in youth. Society for Research on Nicotine and Tobacco. New Orleans, February 20, 2003.

Henningfield, J.E. Introduction to C. E. Koop for Keynote Lecture. Society for Research on Nicotine and Tobacco. New Orleans, February 20, 2003.

Henningfield, J.E. and Santora, P. Reducing drug addiction and abuse: innovations, issues and questions. The Dr. Lonnie E. Mitchell National HBCU Substance Abuse Conference. Baltimore, April 4, 2003.

Henningfield, J.E. and Henningfield, V.B. Tobacco and kids. Friends School third grade class. Baltimore, April 7, 2003.

Henningfield, J.E. and Santora, P. Vaccines and depot medications: Discussion of science foundation, regulation and actual use considerations. Workshop on Immunotherapies and Depot Medications for Treating Drug Addiction. National Academies of Science. Washington DC, April 22, 2003.

Henningfield, J.E. Keynote address: Nicotine addiction as a brain disorder: Implications for public health and policy. Addiction Treatment Providers of New Jersey. Atlantic City, April 29, 2003.

Henningfield, J.E. and Santora, P. Tobacco addiction: Science, Medicine and Policy. Department of Psychiatry and Behavioral Sciences Biennial Program. Baltimore, May, 1, 2003.

Henningfield, J.E. (along with Carlo DiClemente, Mark Fishman, and Terry Fitzgerald, with host Andy Bienstock). The nature of addiction and methods of treatment. The Marc Steiner Show, WYPR-FM, 88.1, radio. Baltimore, MD, May 13, 2003.

Henningfield, J.E. Invited testimony for hearing: Reduce exposure/reduced risk tobacco products: An examination of the potential public health impact and regulatory challenges. U.S. House of Representatives, Committee on Government Reform. Washington, DC, June 3, 2003.

Henningfield, J.E. New tobacco and nicotine products: snake oil or harm reduction? Tobacco Control Research: Investing in Science for the Public's Health. Washington DC, June 19, 2003.

Henningfield, J.E. Tobacco addiction and treatment: The science foundation. An educational briefing for the Health, Education, Labor and Pensions Committee Staff of the United States Senate concerning Senate staff involved in development of the "Family Smoking Prevention and Tobacco Control Act" and other tobacco legislation. Hart Senate Building, Washington, DC, July 31, 2003.

Henningfield, J.E. International tobacco product regulation, scientific issues and questions: Bridging scientific uncertainty. World Health Organization workshop: Protocols to the Framework Convention on Tobacco Control (FCTC). 12th World Conference on Tobacco or Health. Helsinki, Finland, August 4, 2003.

Henningfield, J.E. Plenary Session Keynote: Tobacco addiction: control by product regulation. 12th World Conference on Tobacco or Health. Helsinki, Finland, August 6, 2003.

Anderson, P. and Henningfield, J.E., Co-chairs, Defining and measuring a good quality service for the treatment of tobacco dependence. 12th World Conference on Tobacco or Health, Helsinki. Finland, August 6, 2003.

Henningfield, J.E. Tobacco harm reduction products: Core principles. 12th World Conference on Tobacco or Health, Helsinki, Finland. August 7, 2003.

Henningfield, J.E. Tobacco addiction, regulation and policy. University of Maryland Law School, Baltimore, Maryland, September, 2, 2003.

Henningfield, J.E. and Markou, A. (with G.F. Koob as co-author). Implications of Neurobiology for tobacco control (presented by JEH), and Neurobiology of nicotine addiction (presented by AM). World Bank and World Health Organization Global Workshop on Nicotine Addiction (Sponsored by University of Toronto, Tata Institute for Fundamental Research, NIH, and Bill and Melinda Gates Foundation), Mumbai, India, September 22-23, 2003.

Henningfield, J.E. and Zeller, M. Regulatory issues to be considered in light of the WHO Framework Convention on Tobacco Control (FCTC). World Health Organization Scientific Advisory Committee on Tobacco Regulation, 6th Session, Goa, India, September 25-27, 2003.

Henningfield, J.E. Tobacco dependence and other drug dependencies. International Council on Alcohol and Addictions, Toronto, Canada, October 20, 2003.

Henningfield, J.E. Introduction, moderator and closing comments. First Annual Innovators Awards Program Lectureship – Addiction treatment in the 21st century: lessons from mainstream medicine, by A. Thomas McLellan. Johns Hopkins University School of Medicine, Baltimore, November 10, 2003.

Henningfield, J.E. Tobacco and other addictions: Research and policy issues. Morgan State University, Center for Health Disparities Solutions Lecture Series. Baltimore, December 4, 2003.

Henningfield, J.E. FDA Regulation: Laboratory Capacity and science needs. National Conference on Tobacco or Health, Boston, December 11, 2003.

Henningfield, J.E. New tobacco and nicotine products: Snake oil or harm reduction. National Conference on Tobacco or Health, Boston, December 11, 2003.

Henningfield, J.E. Contributions of John Slade to the control of substance abuse and tobacco addiction. National Conference on Tobacco or Health, Boston, December 12, 2003.

Henningfield, J.E. Smokeless tobacco: Product science and actual use issues. National Conference on Tobacco or Health, Boston, December 12, 2003.

Henningfield, J.E. The changing cigarette and harm reduction. Johns Hopkins Bloomberg School of Public Health, Institute for Global Tobacco Control lecture series, Baltimore, January 28, 2004.

Henningfield, J.E. Panelist/Discussant. 40 years of progress on smoking and health: Lessons from the past, opportunities for the future. Scottsdale, Arizona, February 18, 2004.

Henningfield, J.E. and Zeller, M. Science base for regulating tobacco addiction liability. Society for Research on Nicotine and Tobacco, Annual Meeting. Scottsdale, Arizona, February 19, 2004.

Wayne, G.F., Connolly, G.N. and Henningfield, J.E. Tobacco industry documents as a roadmap for exploring the neurobiology of tobacco dependence. Society for Research on Nicotine and Tobacco, Annual Meeting. Scottsdale, Arizona, February 19, 2004.

Henningfield, J.E. Tobacco addiction and disease: A public health framework. Who's in Control: Cigarettes or Citizens? Tobacco and Disease, Behavior at the Crossroads of Public Health Lecture Series. Johns Hopkins Bloomberg School of Public Health, Baltimore, March 5, 2004.

Henningfield, J.E. Science base for tobacco regulation, disease control and treatment. Dean's lecture and visiting professor program, University of Kentucky College of Medicine, Lexington, March 9, 2004.

Henningfield, J.E. Nicotine Pharmacology. Medical Pharmacology Course, Johns Hopkins University School of Medicine, Baltimore, March 11, 2004.

Henningfield, J.E. Drug Addiction: Developing compassion for people afflicted by drug addiction. World Addiction Foundation Inaugural Dinner and Conference, Livingston, New Jersey, March 24, 2004.

Henningfield, J.E. Tobacco research, testing, and capacity building needs. International Network for Tobacco Testing, Research and Regulation (INTTRR), World Health Organization and National Cancer Institute Joint Meeting, Rockville, Maryland, March 25, 2004.

Santora, P., Dorsey-Jackson, M. and Henningfield, J.E. Co-curator's and moderators: Addiction and Art – a juried exhibition. The Dr. Lonnie E. Mitchell National HBCU Substance Abuse Conference, Baltimore, March 30 – April, 2, 2004.

Henningfield, J.E. The importance of mentoring in drug addiction control including comments from Dr. C.Everett Koop. Reckitt Benckiser Inaugural Mentor/Speaking Program. New Orleans April 17, 2004.

Henningfield, J.E. Tobacco and Disease Overview. Charting a New Course: The Way Forward, Behavior at the Crossroads of Public Health Lecture Series. Johns Hopkins Bloomberg School of Public Health, Baltimore, May 17, 2004.

Henningfield, J.E. Controlling substance abuse and addiction: 21st century challenges. Developing Leadership in Substance Abuse and Innovators Combating Substance Abuse Joint Annual Meeting, Chicago, May 19, 2004.

Henningfield, J.E., Rose, C.A. and Zeller, M. Judge for yourself: An analysis of tobacco industry's statements to juries on matters of addiction. Depositions and Trial Testimony Archive (DATTA) and Tobacco Products Liability Project Joint Meeting, San Diego, June 1, 2004.

Henningfield, J.E. Introduction and Moderator. First Innovators Awards Program Think Tank: Protecting the privacy of drug addicted persons in treatment can serve as a barrier to diagnosis and treatment: Intended and unintended consequences of Federal Regulation 42 CFR Part 2 and the Health Insurance Portability and Accountability Act. Robert Wood Johnson Foundation, April 22, 2004.

Henningfield, J.E. Introduction and Moderator. Second Innovators Awards Program Think Tank. Drug addiction treatment in the 21st century: Issues and challenges to making addiction treatment as accessible as addictive drugs. Adjunct to the Annual Meeting of the College on Problems of Drug Dependence, San Juan, Puerto Rico, June 15, 2004.

Henningfield, J.E. Reducing tobacco addiction and disease: Science, medicine and policy. Tobacco Control Research Seminar and Visiting Professor Series, Center for Tobacco Research and Intervention, University of Wisconsin School of Medicine, Madison, June 24, 2004.

Henningfield, J.E. Discussant: Medications for tobacco addiction treatment: expanding the options. National Cancer Institute, National Institute on Drug Abuse, and National Institute on Alcohol and Alcoholism. Bolger Center, Potomac, Maryland August 24, 2004.

Koop, C.E. and Henningfield, J.E. Developing leadership in public health. Dartmouth College, Hanover, October 22, 2004.

Henningfield, J.E. Introduction and Moderator: Treating tobacco addiction: Effective Strategies for the 21st Century. Second Annual Innovators Awards Program Lectureship by Michael C. Fiore with commentary by Scott J. Leischow. The Johns Hopkins University School of Medicine, Baltimore, November 10, 2004.

Henningfield, J.E. Tobacco Addiction: Science Foundation for Public Health Policy. Columbia School of Medicine and School of Public Health joint conference. New York, February 10, 2005.

Henningfield, J.E. Nicotine Pharmacology. Medical Pharmacology course, The Johns Hopkins University School of Medicine, Baltimore, March 15, 2005.

Henningfield, J.E. New Tobacco and Nicotine Products: Snake Oil or Harm Reduction. Medical University of Vienna, Institute for Social Medicine, Nicotine Institute. Vienna, March 18, 2005.

Henningfield, J.E., Fant, R. Zeller, M., Gitchell, J., and Pinney, J. How might FDA apply principles of risk management prior to permitting health claims for smokeless tobacco as part of a harm reduction strategy? Society for Research on Nicotine and Tobacco. Prague, March 23, 2005.

Henningfield, J.E. Discussant. Opioid Risk Management. Tufts Health Care Institute. Boston, March 29, 2005.

Henningfield, J.E. Moderator and Introduction: Expecting the Unexpected: Effective Utilization of Risk Management. Also presenting: Risk Management Issues: an Overview; Risk Management: An FDA Perspective as Interpreted by Jack E. Henningfield. With J.D. Haddox and R.S Morey. Food and Drug Law Institute Meeting. Washington DC, April 8, 2005.

Henningfield, J.E., Cone, E.J, Fant, R.V. Sees, K. and Pinney, J.M. Risk Management Solutions for Novel Formulations: Path to More Flexible CSA Scheduling Options? Impact of Drug Formulation on Abuse Liability Safety and Regulatory Decisions Conference. College on Problems of Drug Dependence. Bethesda, April 19-20, 2005.

Henningfield, J.E. and Santora, P.B. Co-Chair and Moderate Judges Session for 2nd Annual Addiction Art Juried Competition at the American Visionary Arts Museum for The 7th Annual Dr. Lonnie E. Mitchell National HBCU Substance Abuse Conference. Baltimore, April 22, 2005.

Henningfield, J.E. and Zaatari, G. Recommendations for WHO scientific advisory on the health effects of waterpipe smoking. WHO TobReg 2nd Meeting, Rio de Janeiro, Brazil, June 7-9, 2005.

Henningfield, J.E. and Stolerman, I. Co-Chairs and Introduction to Plenary Symposium: Nicotine Psychopharmacology and Policy – A Look Behind and a Look Ahead. American Psychological Association, National Meeting, Washington, DC, August 18, 2005.

Henningfield, J.E. and Zeller, M. Psychopharmacology Research Implications for National and Global Tobacco Regulation. Presented in Plenary Symposium: Nicotine Psychopharmacology and Policy – A Look Behind and a Look Ahead. American Psychological Association, Washington, DC, August 18, 2005.

Henningfield, J.E. Tobacco Addiction: Interface Between Tobacco and Cancer. Symposium on Tobacco Carcinogenesis. American Chemical Society, National Meeting, Washington, DC, August 30, 2005.

Henningfield, J.E. Changing Nature of Nicotine. Keynote at American Osteopathic Academy of Addiction Medicine, Annual Scientific Convention of the American Osteopathic Association, Orlando, October 24, 2005 – Delivered via telephone remote with Dr. Sees presenting abbreviated slide set due to Hurricane Wilma.

Henningfield, J.E. Moderator and Introduction to Alcohol screening, intervention and confidentiality requirements in trauma centers and emergency departments. Johns Hopkins University School of Medicine Third Annual Symposium of the Innovators Awards Program, Baltimore, October 26, 2005.

Henningfield, J.E. Nicotine Pharmacology. Medical Pharmacology Course, Johns Hopkins University School of Medicine, Baltimore, November 15, 2005.

Henningfield, J.E. Chairman, Expert Committee on Health and Smoking, Japan-U.S. Seminar for Treating Smokers. Tokyo Prince Hotel Park Tower, Tokyo, November 21, 2005.

Henningfield, J.E. The neurophysiology of tobacco dependence and implications for treatment. Tokyo Prince Hotel Park Tower, Tokyo, November 21, 2005.

Henningfield, J.E. Nicotine maintenance for the future. Plenary Session. Third Australian Tobacco Control Conference, Sydney, November, 24, 2005.

Henningfield, J.E. Nicotine facts versus fiction. Breakfast session: Does nicotine need a new publicist? Third Australian Tobacco Control Conference, Sydney, November, 25, 2005.

Henningfield, J.E. Discussant. Tobacco Harm Reduction Strategic Dialogue and Network Meeting, Boston, December 5-7, 2005.

Henningfield, J.E. Distinguished Visiting Scholar, Kansas University Medical Center Series. Tobacco addiction in the 21st century: Science, health, product change and global regulation, Kansas City, Kansas, January 11, 2006.

Henningfield, J.E. All tobacco products are deadly and addictive: Product diversity challenges for regulation and communication. In Technical Briefing for the 1st Session of the Conference of Parties to the World Health Organization Framework Convention on Tobacco Control, Technical Briefing: Tobacco Product Regulation and its Ramifications for Implementation. International Conference Centre Geneva (CICG), Geneva, February 7, 2006.

Henningfield, J. Djordjevic, M., Dybing, E. and Bettcher, D. World Health Organization Tobacco Laboratory Network (WHO TobLabNet). Society for Research on Nicotine and Tobacco, Orlando, February 16, 2006.

Henningfield, J.E. The courtroom is not a laboratory: How science is used in the court of law. In Workshop 2: Science and the courts: How science impacts tobacco litigation. Society for Research on Nicotine and Tobacco, Orlando, February 17, 2006.

Henningfield, J.E. Reducing tobacco use in the 21st century: Virginia from a national and global perspective. Keynote address, The Forum on Youth Tobacco Use: Translating Research into Practice, Richmond, March 29-30, 2006.

Henningfield, J.E. Science Base for Tobacco Control Policy. Seminar on Health Services Research in Policy. George Washington University School of Public Health, Washington, D.C., April 10, 2006.

Henningfield, J.E. What form of scenario planning will be most helpful to overall effort? Strategic dialogue on tobacco harm reduction. Harrison Conference Center, Lake Bluff, IL, May 1-3, 2006.

Schnoll, S.H., Fant, R.F. and Henningfield, J.E. Prescription drug abusers: Abuse is not abuse is not abuse. College on Problems of Drug Dependence. Scottsdale, Arizona, June 21, 2006.

Henningfield, J.E., Fant, R.F. and Schnoll, S.H. Risk management and drug abuse research: challenges and opportunities. College on Problems of Drug Dependence. Scottsdale, Arizona, June 21, 2006.

Henningfield, J.E. Discussant and working group chair: Ingredients and design features related to addictiveness. World Health Organization Tobacco Product Regulation Study Group (TobReg). International Conference Center, Kobe, Japan, June 28-30, 2006.

Henningfield, J.E. Nicotine and mental acuity. Global University on Smoking Control, for GlaxoSmithKline Consumer Healthcare. Lansdowne, VA, July 11, 2006.

Henningfield, J.E. Harm reduction by nicotine delivery (session chair and introduction). 13th World Conference on Tobacco OR Health. Washington, DC, July 14, 2006.

Henningfield, J.E. World Health Organization Consultation on Tobacco Harm Reduction (Rapporteur). Washington, DC, July 15-16, 2006.

Henningfield, J.E. Prescription opioid abuse: science, public health and policy. American Psychological Association. New Orleans, August 12, 2006.

Henningfield, J.E. (Planning Committee Co-Chair with Michael Fiore) Healthcare for the 21st Century: A Celebration of Dr. C. Everett Koop's 90th Birthday. Event Co-Chairs: Senator Orrin G. Hatch and Senator Hillary Rodham Clinton. Cosmos Club, Washington, DC, September 13, 2006.

Henningfield, J.E. Can we reduce the addictiveness of tobacco products? Science, health and policy considerations. Can We Make Smoking History in our Lifetime? Science and Policy Needs. Harvard School of Public Health, Boston, September 18, 2006.

Henningfield, J.E. Tobacco product contents and design: Implications for initiation, addictiveness and toxicity. Third Meeting of the Key Facilitators, Interim Convention of the Secretariat, World Health Organization Tobacco Free Initiative, Framework Convention on Tobacco Control. Ottawa, Canada, October 26, 2006.

Henningfield, J.E. Introduction and Discussion: Innovators Awards Annual Lectureship by Mark W. Parrino: Opioid addiction treatment in the criminal justice system; commentary by The Honorable Karen Freeman-Wilson and Chief of Corrections, Orange County, FL, Timothy P. Ryan. The Johns Hopkins University School of Medicine, Baltimore, November 8, 2006.

Henningfield, J.E. Drug abuse liability assessment, drug scheduling and risk management. Breakfast Roundtable Lecture and Discussion for the Gerson Lehrman Group, New York, November 15, 2006.

Henningfield, J.E., Passik, S., Dhingra, L., Schnoll, and Shiffman, S. Cigarette smoking predicts opioid abuse among pain patients: Clinical and research issues. American College of Neuropsychopharmacology, Hollywood, Florida, December 5, 2006.

Henningfield, J.E. Science base for tobacco addiction and treatment. Smoking Cessation Consensus Panel, National Medical Association. Sonoma, California, December 8, 2006.

Henningfield, J.E. Harm reduction: Promise and peril. Translational medication development for nicotine dependence workshop. National Institute on Drug Abuse and National Cancer Institute, Chevy Chase, Maryland. January 8, 2007.

Henningfield, J.E. Addiction biology and tobacco product design: Formidable barriers to cancer control. President's Cancer Panel: Promoting Healthy Life Styles to Reduce the Risk of Cancer. Jackson, Mississippi, February 12, 2007.

Henningfield, J.E., Passik, S., Dhingra, L, Schnoll, S.H. and Shiffman, S. Tobacco Dependence Marks Prescription Opioid Misuse: Theoretical Basis and Research Agenda. Society for Research on Nicotine and Tobacco, Austin, TX , February 22, 2007.

Henningfield, J.E. with McHugh, P.R. Tobacco addiction: psychiatric considerations before the Motivated Behaviors Medical Rounds Seminar, Johns Hopkins Hospital, Baltimore, March 7, 2007.

Henningfield, J.E. Tobacco Addiction: Science, Medicine and Regulatory Policy. Medical Pharmacology and First Day Series, The Johns Hopkins University School of Medicine, Baltimore, March 13, 2007.

Henningfield, J.E. Tobacco Addiction and Disease Control in the 21st Century: Science, Health and Regulatory Issues. National Institute on Drug Abuse, Intramural Research Program Seminar Series, Baltimore, May 1, 2007.

Henningfield, J.E. Introduction to 6th Annual Marian W. Fischman Memorial Lectureship Award winner, Dorothy K. Hatsukami. College on Problems of Drug Dependence, Quebec City, June 18, 2007.

Fant, R.V., Green, Y., Schnoll, S.H., Henningfield, J.E., Ertischek, M.E. and Cone, E.J. Monitoring the Internet for prescription drug misuse and tampering. College on Problems of Drug Dependence, Quebec City, June 19, 2007.

Schnoll, S.H., Ertischek, M.D., Henningfield, J.E., Fant, R.V., and Rohay, J.M. Prescription drug abuse: Looking beyond the hyperbole. Monitoring the Internet for prescription drug misuse and tampering. College on Problems of Drug Dependence, Quebec City, June 19, 2007.

Henningfield, J.E. Introduction to Art and Addiction Exhibition and Meet the Artists Sessions: Nancy D. Campbell, Ph.D., historian, and Samuel T. Barnes, M.D., sculptor artist at the Quebec Hilton, College on Problems of Drug Dependence, Quebec City, June 18-19, 2007.

Henningfield, J.E. Introduction to Dorothy K. Hatsukami for the 6th Annual Marian W. Fischman Memorial Lectureship Award College on Problems of Drug Dependence, Quebec City, June 18, 2007.

Henningfield, J.E. Presentation: Post 13th World Conference on Tobacco or Health World Health Organization Consultation on Tobacco Harm Reduction. Discussant: Presentation by WHO's Willem Scholten on The WHO Expert Committee on Drug Dependence and its Intersection with the WHO TobReg on the Matter of Nicotine. Chair: Working Group II, TobReg Recommendation on Harm Reduction, PREPS, and Smokeless Tobacco Products. Fourth Meeting of the WHO TobReg, Stanford, California, July 25-27, 2007.

Henningfield, J.E. Discussant, Strategic Dialogue on Tobacco Harm Reduction. Englewood, Colorado, August 1-3, 2007.

Henningfield, J.E. Presenter and Discussant (with David Ashley, David Burns, Erik Dybing, Antoon Opperhuizen and Gemma Vestal, WHO TobReg). Fourth Meeting of the Working Group Convened to Elaborate Guidelines for the Implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control. European Commission Centre Albert Borschette, Brussels, Belgium, September 26-28, 2007.

Henningfield, J.E. Keynote Address: Tobacco Addiction: Science Base for Treatment and Policy. American College of Osteopathic Internists, Boston, October 11, 2007.

Henningfield, J.E., and Vestal, G., Representing World Health Organization Study Group on Tobacco Product Regulation (TobReg). Global Perspective: WHO Study Group on Tobacco Product Regulation. National Conference on Tobacco or Health, Preconference by the Strategic Dialog on Harm Reduction: Reduce the Harm From Tobacco: A Strategic Vision and Blueprint for Action, Minneapolis, 23, 2007.

Henningfield, J.E., Jarvis, M., Dybing, E., Vestal, G., and Bettcher, D. (on behalf of the World Health Organization Study Group on Tobacco Product Regulation – TobReg). Society for Research on Nicotine and Tobacco, Annual Meeting, Portland, OR, February 28, 2008.

Henningfield, J.E., and Vestal, G. (on behalf of the World Health Organization Study Group on Tobacco Product Regulation – TobReg). Global Perspective: WHO Study Group on Tobacco

Product Regulation, presented in Symposium: Reduce the Harm From Tobacco: A Strategic Vision and Blueprint for Action. Society for Research on Nicotine and Tobacco, Annual Meeting, Portland, OR, February 27, 2008.

Henningfield, J.E. on behalf of Purdue Pharma. Prescription drug abuse trends, definitions and concepts. Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Joint Meeting of the Anaesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee hearing to consider a New Drug Application for an Extended Release Formulation of OxyContin, Rockville, MD, May 5, 2008.

Santora, P. and Henningfield, J.E. Addiction Art Exhibition. Substance Abuse and Mental Health Services Administration, Rockville, MD, May 6-16, 2008.

Schnoll, S.H., Fant, R.V., Ertischek, M.E., Buchman, A.C., Henningfield, J.E. Monitoring of federal surveys as part of a risk evaluation and mitigation strategy component: applications and limitations. Presented at the annual meeting of the College on Problems of Drug Dependence, San Juan, Puerto Rico, June 14-19, 2008.

Fant, R.V., Schnoll, S.H., Buchman, A.C., Henningfield, J.E. Fentanyl-related deaths: abuse and off-label use of licit and illicit sources of fentanyl. Presented at the annual meeting of the College on Problems of Drug Dependence, San Juan, Puerto Rico, June 14-19, 2008.

Henningfield, J.E. Smokeless tobacco use and nicotine dependence. Presented at The Cigarette Industry's Entry into the Smokeless Tobacco Market. Harvard School of Public Health, Boston, July 10, 2008.

Koop, C.E. and Henningfield, J.E., Co-Chairmen, Insights and Images of the Brain in Withdrawal: Clinical Strategies to Improve Outcomes in Smoking Cessation. Satellite symposium to the Annual Meeting of the American Academy of Family Physicians, San Diego, September 17, 2008.

Henningfield, J.E. Cognitive deficits from smoking cessation. In: Insights and Images of the Brain in Withdrawal: Clinical Strategies to Improve Outcomes in Smoking Cessation. Satellite symposium to the Annual Meeting of the American Academy of Family Physicians, San Diego, September 17, 2008.

Schuster, C.R. and Henningfield, J.E. Introduction to the Conference and Co-Chairs Expert Panel. College on Problems of Drug Dependence Conference on Risk Management and Postmarketing Surveillance of CNS Drugs (R.L. Balster and J.E. Henningfield, Planning Committee), Rockville, Maryland, October 27-28, 2008.

Henningfield, J.E. and Schuster, C.R. Commentary on risk management of CNS drugs. College on Problems of Drug Dependence Conference on Risk Management and Postmarketing Surveillance of CNS Drugs, Rockville, Maryland, October 27-28, 2008.

Henningfield, J.E. Electronic nicotine delivery systems. World Health Organization Tobacco Regulation Study Group (WHO TobReg). Durban, South Africa, November 12-14, 2008.

Henningfield, J.E. Risk evaluation and mitigation strategies (REMS): Focus on CNS Drugs. American Course on Drug Development and Regulatory Sciences, University of California, San Francisco. Presented in Washington, DC, January 14, 2009.

Henningfield, J.E. Nicotine Pharmacology – Tobacco addiction: science, medicine and regulatory policy. The Johns Hopkins University School of Medicine, March 3, 2009.

Henningfield, J.E. FDA Opioid REMS development: Implications of CPDD special meeting on risk management and post-marketing surveillance. Center for Drug Evaluation and Research (CDER), Food and Drug Administration, Public Meeting on Risk Evaluation and Mitigation Strategies (REMS) for Certain Opioids, Gaithersburg, MD, May 28, 2009.

Hatsukami, D. and Henningfield, J.E. (Co-chairs). Regulating nicotine in tobacco products: State of the science and future policy. Symposium presented at the Annual Meeting of the College on Problems of Drug Dependence, Reno, NV, June 24, 2009.

Sellers, E.M. and Henningfield, J.E., (Co-chairs). Fit to be tied: Abuse potential of antiepileptics. Workshop presented at the Annual Meeting of the College on Problems of Drug Dependence, Reno, NV, June 21, 2009.

Lo, S.J., Collins, C., Henningfield, J.E., Moolchan, E. Adolescent tobacco initiation, use and ongoing nicotine addiction: Perspectives on a reduced nicotine content policy. Presented at the Annual Meeting of the College on Problems of Drug Dependence, Reno, NV, June 25, 2009.

Henningfield, J.E. Are e-cigarettes a bridge product to smoking or abstinence? Or neither? Position of the World Health Organization, Tobacco Product Regulation Study Group. Legacy 10-Year Anniversary Thought Leader Series, Kenneth Warner Lecture Series at the American Legacy Foundation. Washington D.C., Webcast September 16, 2009.

Henningfield, J.E. Keynote address: Smokeless tobacco: The true risks, new challenges and opportunities. Fifth National Summit on Smokeless and Spit Tobacco, Madison, WI, September 21, 2009.

Henningfield, J.E. Menthol cigarettes: scientific, public health, social and regulatory issues. A Town Hall Meeting on Menthol Cigarettes. The Howard University College of Medicine, Washington DC, October 19, 2009.

Henningfield, J.E. Menthol in tobacco: FDA considerations. Second Conference on Menthol Cigarettes, Washington, DC, October 20, 2009.

Henningfield, J.E. Tobacco product characteristics: Implications and challenges for labelling. Cigarette Warning Labels, Packaging & Product Labelling: Current Science & Practice to Identify Research Priorities. National Cancer Institute, Rockville, Maryland, October 21, 2009

Henningfield, J.E., Addiction and Art. Madness and Obsession: Series Celebrating Poe's 200th Anniversary. Baltimore Museum of Art and Art on Purpose, Baltimore, Maryland, November 1, 2009.

Henningfield, J.E., Zaatari, G.S. and Vestal, G. "E-Cigs" are electronic nicotine delivery systems (ENDS): Conclusions and recommendations for research and policy by the World Health Organization Tobacco Regulation (WHO TobReg) Study Group. Presented at the annual meeting of the Society for Research on Nicotine and Tobacco, Baltimore, February 26, 2010.

Henningfield, J.E. (Presenter and Discussant/Rapporteur. The science of abuse liability assessment applied to tobacco products. Conference on Abuse Liability and Consumer Appeal of Tobacco Products: Science and Future Directions. Rockville, Maryland, April 8-9, 2010.

Henningfield, J.E., Fant, R., and Heal, D.J. Comparison of European and U.S. approaches to the evaluation of abuse liability and drug scheduling for new chemical entities (NCEs). College on Problems of Drug Dependence. Scottsdale, Arizona, June 13-17, 2010.

Henningfield, J.E., Threading the needle: Translation from science through regulation to marketing. In symposium entitled: Hair of the dog: Agonists for stimulant dependence. College on Problems of Drug Dependence. Scottsdale, Arizona, June 13-17, 2010.

Henningfield, J.E., Fant, R., Schnoll, S., and Sembower, M. Prescription opioids: Managing the risks while maintaining appropriate patient access. College on Problems of Drug Dependence. Scottsdale, Arizona, June 13-17, 2010.

Schuster, C.R., Henningfield, J.E., Balster, R.L., Barthwell, A.G., and Johanson, C.E. The CPDD special conference on risk management and post-marketing surveillance of CNS drugs: Implications for Opioid REMS. College on Problems of Drug Dependence. Scottsdale, Arizona, June 13-17, 2010.

Henningfield, J.E. Smokeless tobacco: Addictive by nature and design. Governor's Oral Health Summit. North Little Rock, Arkansas, June 18, 2010.

Henningfield, J.E. FDA Brady-Schuster Award Lecture: Tobacco Science, Public Health and Policy: It Takes a Community. American Psychological Association, San Diego, August 12, 2010.

Henningfield, J.E. Tobacco Addiction: Science, Public Health & FDA Regulation. Charles Drew University Substance Abuse Research Day, Los Angeles, CA, August 13, 2010.

Henningfield, J.E. FDA Tobacco Regulation: Policy Implications of Behavioral Research. Presented in the Symposium: Psychopharmacology and Public Policy. American Psychological Association, San Diego, August 14, 2010.

Henningfield, J.E. Tobacco Addiction: Science, Public Health, and Policy. The Johns Hopkins Bloomberg School of Public Health, Video Lecture, Baltimore, September 8, 2011.

Henningfield, J.E. Discussion of the Rationale Basis for a Regulatory Framework to Reduce the Dependence Potential of Tobacco Products. World Health Organization, Tobacco Product Regulation Study Group, 6th Meeting, Buenos Aires, Argentina, November 22-24, 2010.

Henningfield, J.E. FDA Tobacco Regulation: Policy Implications of Behavioral Research. The Johns Hopkins University School of Medicine, Baltimore, January 19, 2011.

Henningfield, J.E., Fant, R.V. and Buchhalter, A. Evaluation of Complex Drug Formulations and Tobacco Products: Challenges to Traditional Behavioral Pharmacology. Behavioral Pharmacology Society. Washington, D.C., April 9, 2011

Henningfield, J.E. Advancing Public Health: Promoting Healthy Behavior. Introduction to topic and to the State of Maryland Deputy Secretary for Behavioral Health and Disabilities, Renata J. Henry. Advancing Public Health and Safety – It's All About Behavior. 50th Anniversary Conference, the Joseph V. Brady Institutes for Behavioral Resources. The Johns Hopkins University School of Medicine, Baltimore, May 2, 2011.

Henningfield, J.E. Behavioral Science Contribution to Drug Regulation – Assessing Abuse Potential. Introduction to topic and to Dr. Silvia Calderon, Controlled Substances Staff, Food and Drug Administration. Advancing Public Health and Safety – It's All About Behavior. 50th Anniversary Conference, the Joseph V. Brady Institutes for Behavioral Resources. The Johns Hopkins University School of Medicine, Baltimore, May 2, 2011.

Henningfield, J.E. Tobacco is Naturally Harmful and Addictive: Cigarettes are Deceptive and Far More Addictive by Design. Campaign for Tobacco Free Kids, Washington, D.C., May 18, 2011.

Henningfield, J.E. Tobacco Addiction Science Advances: Implications for Treatment, Regulation and Research. The Johns Hopkins University School of Medicine, Baltimore, May 17, 2011.

Henningfield, J.E., Tobacco Product Abuse Liability Assessment: The State of the Science and Challenges to Regulation. Harvard School of Public Health, Boston, May, 25, 2011.

Henningfield, J.E., Fant, R.V. and Buchhalter, A. International Study Group Investigating Drugs as Reinforcers. Hollywood, Florida, June 17, 2011.

Henningfield, J. Gray, N, Zaatari, G. and Bettcher, D. Tobacco Product Dependence Liability Assessment to Support the WHO Framework Convention on Tobacco Control (WHO FCTC). College on Problems of Drug Dependence, Hollywood Florida, June 18-23, 2011.

Hatsukami, D. and Henningfield, J. (Co-chairs) Symposium on Abuse Liability and Product Appeal Assessment of Tobacco. College on Problems of Drug Dependence, Hollywood Florida, June 18-23, 2011.

Henningfield, J.E. – in collaboration and on behalf of Charles R. Schuster. Post Marketing Surveillance Risk Management Approaches Applied to Tobacco. In the Symposium on Abuse Liability and Product Appeal Assessment of Tobacco. College on Problems of Drug Dependence, Hollywood Florida, June 18-23, 2011.

Schnoll, S., Fant, R.V., Ertischek, M.E., and Henningfield, J.E. Risk Evaluation and Mitigation Strategies (REMS): New Opportunities and Challenges for Drug Abuse Investigators. College on Problems of Drug Dependence, Hollywood Florida, June 18-23, 2011.

Henningfield, J. Gray, N, Zaatari, G. and Bettcher, D. Tobacco Product Dependence Liability Assessment to Support the WHO Framework Convention on Tobacco Control (WHO FCTC). College on Problems of Drug Dependence, Hollywood Florida, June 18-23, 2011.

Henningfield, J.E., The Science Base and Regulatory Precedent for Regulating Tobacco Product Addictiveness. Harvard School of Public Health, Boston, June 22, 2011.

Henningfield, J.E. Novel Drug and Tobacco Formulations: Challenges to Behavioral Pharmacological Analysis. Training in Behavioral Pharmacology of Drug Dependence, 21st Annual Scientific Trainee Retreat. University of Vermont, Burlington, August 16-17, 2011

Henningfield, J.E. Advancing Public Health by Regulating the Addictiveness of Tobacco Products. The Johns Hopkins Bloomberg School of Public Health, FAMRI Center of Excellence Lecture. Johns Hopkins, Baltimore, September 29, 2011.

Henningfield, J.E. Tobacco Addiction Science: Implications for International Control Under the Framework Convention. Premeeting Symposium: Reducing the Harm Caused by Abused Drugs: Putting Science into Public Policy, American Academy of Clinical Toxicology, North American Congress of Clinical Toxicology, Washington, D.C., September 21, 2011.

FDA Regulatory Authority Over Tobacco: A Science and Advocacy Success Story – Keynote Lecture Following Presentation of Presidential Citation Award by APA President Melba Vasquez. American Psychological Association, Science Leadership Conference. Washington D.C., October 23, 2011.

Henningfield, J.E., Cone, E., Schnoll, S., Buchhalter, A., Fant, R. and Webster, L. Human subject abuse potential studies: evaluation of complex formulations and its special challenges. Science of Abuse Liability Assessment Conference, convened by the FDA, NIDA and CPDD, Rockville, November 10, 2011.

Henningfield, J.E. and Santora, P.B. Art and Addiction. Sponsored by MICA's Community Arts Partnership and Tuerk House Substance Abuse Treatment and Recovery. Maryland Institute College of Art, Falvey Hall, Brown Center, Baltimore, November 10, 2011.

Henningfield, J.E. Determinants of the addictiveness of tobacco products: implications for reducing addiction risk. Campaign for Tobacco Free Kids, Washington, D.C., November 29, 2011.

Henningfield, J.E. Tobacco product dependence potential reduction by control of content and design. World Health Organization Framework Convention on Tobacco Control. Seventh Meeting of the Working Group on Articles 9 and 10 of the WHO FCTC, World Health Organization, Geneva, Switzerland, January 24-26, 2012.

Webster, L. and Henningfield, J.E. Regulatory and scientific challenges in abuse liability assessment. Association of Clinical Pharmacology Units Annual Meeting, Bethesda, MD, April 25-27, 2012.

Henningfield, J.E. Testimony to provide comment on social science methodologies to assess goals related to knowledge: Strategies for recruitment and sample size considerations. Food and Drug Administration, Public Workshop: Risk Evaluation and Mitigation Strategies (REMS) Assessments: Social Science Methodologies to Assess Goals Related to Knowledge. FDA, Center for Drug Evaluation and Research, Silver Spring, MD, June 7, 2012.

Henningfield, J.E. Bringing NIAAA and NIDA together: Finally – the promise and the peril. In the President's Symposium: Addressing the challenges of tobacco and alcohol use. College on Problems of Drug Dependence, La Quinta Resort, Palm Springs, CA, June 10, 2012.

Henningfield, J.E. Do we under-treat the most prevalent form of substance abuse among pregnant women, Co-Chair (with S.T. Higgins) and Discussant. College on Problems of Drug Dependence, La Quinta Resort, Palm Springs, CA, June 11, 2012.

Cone, E.J., Henningfield, J.E., and Fant, R.V. In Vitro Assessment of Abuse (Tamper) Deterrent Formulations. College on Problems of Drug Dependence, La Quinta Resort, Palm Springs, CA, June 11, 2012.

Henningfield, J.R. (Moderator and Discussant). Nicotine reduction. Workshop on endgame strategies in tobacco control. University of Michigan School of Public Health, Ann Arbor, MI, June 19-21, 2012.

Henningfield, J.E. (Moderator and Presenter, with M. Djordjevic). Scientific basis for regulating novel products being developed/pursued by the tobacco industry. Tobacco Product Regulation, Strategic Planning Meeting. World Health Organization, Geneva, October 11-12, 2012.

Henningfield, J.E. Dissolvable smokeless tobacco products. Tobacco Product Regulation, Strategic Planning Meeting. World Health Organization, Geneva, October 11-12, 2012.

Henningfield, J.E. Abuse liability assessment of opioid analgesics. Closed session of the State Food and Drug Administration, and the Peking University National Institute of Drug Dependence. Beijing, November 4-6, 2012.

Henningfield, J.E., Hursh, S.R., Roma, P.G., Cone, E.J., Buchhalter, A.R., Fant, R.V., and Schnoll, S.H. Behavioral economics for standardized metrics in CNS drug development and regulation. American College of Neuropsychopharmacology. Hollywood, Florida, December 5, 2012.

Henningfield, J.E. (Moderator). Meeting of the Expert Advisory Board to the Center for the Evaluation of Nicotine in Cigarettes (CENIC). Rockville, Maryland December 17, 2012.

Henningfield, J.E. Comments on the contributions of Joseph V. Brady and the Institutes for Behavioral Resources to the improvement of public health. Institutes for Behavioral Resources, Baltimore, December 18, 2012.

Henningfield, J.E., Schnoll, S.H., and Gerlach, K.K. Testimony and comment on proposed modified labeling of opioid analgesics. Food and Drug Administration, Public Hearing and Request for Comments: Impact of Approved Drug Labeling on Chronic Opioid Therapy, Bethesda, Marriott Hotel, February 7-8, 2013 (written comments on PROP Petition to FDA Docket No. FDA-2012-N-1172).

Henningfield, J.E. Introduction to Keynote Lecture by Nigel Gray. Society for Research on Nicotine and Tobacco, Boston, March 14, 2013.

Benowitz, N.L. and Henningfield, J.E. Reducing the nicotine content to make cigarettes less addictive. In Symposium: An Endgame for Tobacco?, K.E. Warner, Chair. Society for Research on Nicotine and Tobacco, Boston, March 15, 2013.

Henningfield, J.E. Discussant for The regulatory science of nicotine reduction: new perspectives, data, and opportunities for animal research. Society for Research on Nicotine and Tobacco, Boston, March 16, 2013.

Henningfield, J.E., Buchhalter, A.R., Cone, E.J., Fant, R.V. and Schnoll, S.S. Abuse-Deterrence Science: Why, When, and What? Roundtable on FDA's Abuse Deterrence Guidance: A Dialogue on Challenges and Opportunities. (Other roundtable participants were: Douglas C. Throckmorton, Andrea G. Barthwell, Paul Coplan, Carlo J. DiFonzo, and Jason Money.) Controlled Substances Regulation. Food and Drug Law Institute Conference. Washington, D.C., March 28, 2013.

Henningfield, J.E. (Reactor) Critical Issues in Scheduling: Case studies. Controlled Substances Regulation. Food and Drug Law Institute Conference. Washington, D.C., March 28, 2013.

Roma, P.G., Henningfield, J.E., Hursh, S.R., Cone, E.J., Buchhalter, A.R., Fant, R.V. and Schnoll, S.H. Applied behavioral economics for evaluating potential labeling claims of abuse-deterrent opioids: A pilot study. International Study Group Investigating Drugs as Reinforcers (ISGIDAR). San Diego, CA, June 15, 2013

Henningfield, J.E. Emerging tobacco products: Perils and potential promise. Workshop XII: Novel Tobacco and Nicotine Products and Regulatory Science. College on Problems of Drug Dependence. San Diego, CA, June 18, 2013

Webster, L.R., Smith, S., Silowsky, J., Gogas, K., Odinecs, A., Eldon, M. Abrouk, N., Medve, R. Henningfield, J., Buchhalter, A., Cone, E., Fant, R., and Schnoll, S. Abuse potential assessment of a novel opioid analgesic NKTR-181: Implications for labeling and scheduling. College on Problems of Drug Dependence. San Diego, CA, June 20, 2013.

Henningfield, J.E. Human abuse liability testing in CNS drug development: Science foundation for drug scheduling. Drug Information Association (DIA) Annual National Meeting. Boston, MA June 25, 2013.

Henningfield, J.E. Tobacco is naturally harmful and addictive: Cigarettes are deceptive and far more addictive by design. Global Seminar, Campaign for Tobacco Free Kids. Washington DC, June 26, 2013.

Henningfield, J.E. Roundtable Discussion, invited participant. Tobacco Product Analysis: A Scientific Public Workshop. Food and Drug Administration, Center for Tobacco Products. Rockville, MD, July 30-31, 2013.

Henningfield, J.E. Nicotine Reduction: How a "radical idea" got mainstream; What might make it possible; and, What we Can Learn From Opioid Regulation? Centers for Disease Control and Prevention Listening Session: E-Cigarettes and Endgame Options. Atlanta, GA. August 19-20, 2013.

Henningfield, J.E. Drug Labeling, Introduction and Session Chair. Abuse Deterrent Formulation Science Meeting: Discussion of the FDA Draft Guidance for Industry: Abuse Deterrent Opioids – Evaluation and Labeling. Organized by the Cross Company Abuse Liability Consortium (CCALC); facilitated with the Aid of the College on Problem of Drug Dependence (CPDD); with presentations by the FDA representatives. Bethesda, MD, September 30- October 1, 2013.

Fant, R.V., Cone, E.J., Henningfield, J.E., Buchhalter, A.R., and Schnoll, S.H. Abuse liability assessment: methods and challenges. Pain Week Annual Meeting. Las Vegas, NV, September 4-7, 2013.

J.E. Henningfield, Tobacco use as an exemplar of what can be accomplished with behavior change: Challenges ahead. Behavior Change, Health, and Health Disparities. Vermont Center on Behavior and Health, University of Vermont, Burlington, VT, September 26, 2013.

Henningfield, J.E. Session and Panel Chair. Drug Labeling Panel Summary, Conclusions and Recommendations. Abuse Deterrent Formulation Science Meeting: Discussion of the FDA Draft Guidance for Industry: Abuse Deterrent Opioids – Evaluation and Labeling. Organized by the Cross-Company Abuse Liability Consortium, Facilitated by the College on Problems of Drug Dependence, and with Presentations by the Food and Drug Administration. Bethesda, MD, September 30 – October 1, 2013.

Cone, E.J. and Henningfield, J.E. Implications of In Vitro Testing Of ADFs For Industry And Real World Abusers. Abuse Deterrent Formulation Science Meeting: Discussion of the FDA Draft Guidance for Industry: Abuse Deterrent Opioids – Evaluation and Labeling. Organized by the Cross-Company Abuse Liability Consortium, Facilitated by the College on Problems of Drug Dependence, and with Presentations by the Food and Drug Administration. Bethesda, MD, September 30 – October 1, 2013.

Henningfield, J.E. Cigarettes: How The Tobacco Industry Made A Bad Product Worse – Implications for Electronic Nicotine And Lessons to Improve Public Health. Bloomberg Philanthropies, New York, October 23, 2013.

Henningfield, J.E. and Wayne, G.F. Reducing the dependence potential of manufactured cigarettes by reducing their nicotine content to levels that cannot cause or sustain addiction. 7th meeting of the WHO Study Group on Tobacco Product Regulation (TobReg), 04-06 December 2013, Rio de Janeiro, Brazil

Henningfield, J.E. and Grana, R. Electronic Nicotine Delivery Systems: Update on Public Health Implications and Recommendations for Research and Policy (based on report by Rachel Grana, Neal Benowitz and Stanton Glantz). 7th meeting of the WHO Study Group on Tobacco Product Regulation (TobReg), 06 December 2013, Rio de Janeiro, Brazil

Henningfield, J.E. (Panelist and Program Committee member) Drug Scheduling: A Roundtable on Challenges and Opportunities --Focus on the Science Base (Panel included: Michael Klein, Ph.D., Director, Controlled Substance Staff, CDER, OCD, FDA, Andrea C. Masciale, Vice President, Regulatory Affairs, Johnson & Johnson, Angela M. Ostrom, Esq., Vice President Public Policy & Advocacy, Epilepsy Foundation, and was moderated by Ginny Beakes- Read, Executive Director, Global Regulatory Policy and Intelligence, Global Regulatory Affairs, Eisai, Inc. February 19, 2014, Washington, DC.

Henningfield, J.E. (Consultant). FDA Tobacco Products Scientific Advisory Committee. Rockville, MD, April 16, 2014.

Henningfield, J.E. Postmarketing Requirements: Challenges to Instrument Validation. FDA Public Meeting on the Postmarketing Requirements for the Extended-Release/Long-Acting Opioid Analgesics. FDA, Silver Spring, MD, May 19, 2014.

Henningfield, J.E. Buchhalter, A.R., Cone, E.J., Fant, R.R. and Schnoll, S.S. FDA Draft Guidance on Abuse Deterrent Opioids – Limiting Reinforcing Effects by Slowing Speed of Delivery to the Brain: Implications for In Vitro, Nonclinical and Clinical Abuse Liability Assessment. International Study Group Investigating Drugs as Reinforcers (ISGIDAR), San Juan, June 14, 2014.

Johnson, M.W., Griffiths, R.R., Henningfield, J.E. and Fant, R.V. Psilocybin Abuse Liability Assessment: Implications for Scheduling if FDA Approves Psilocybin for Medical Use. International Study Group Investigating Drugs as Reinforcers (ISGIDAR), San Juan, June 14, 2014.

Cone, E.J., Henningfield, J.E., and Fant, R.V. In Vitro Assessment of Abuse (Tamper) Deterrent Formulations. College on Problems of Drug Dependence, Workshop Symposium, San Juan, June 15, 2014.

Henningfield, J.E. Marketing E-Cigarettes and Other Tobacco Products to Youth and Young Adults. Texas Tobacco Summit, Houston, June 27, 2014.

Henningfield, J.E., Fant, R.R., Buchhalter, A.R., Cone, E.J., and Schnoll, S.S. FDA 2013 Guidance Encourages Novel Approaches to Abuse Deterrent Drug Development: Challenges and Opportunities in Abuse Liability Science. American Psychological Association, Washington D.C., August 9, 2014.

Henningfield, J.E. Pharmacology and dependence potential of transdermal buprenorphine: Discussion and Conclusions. Recent Advances in Anesthesia and Perioperative Medicine, 2014 Annual Meeting of Taiwan Society of Anesthesiologists, Tungs' MetroHarbor Hospital, Taichung, Taiwan, September 27, 2014.

Henningfield, J.E. Electronic nicotine delivery systems (ENDS): Scientific, public health, and regulatory challenges. Division of Behavioral Biology, Department of Psychiatry and Behavioral Sciences, The Johns Hopkins University School of Medicine, Baltimore, October 8, 2014.

Henningfield, J.E. Comment on implications of FDA Category 1 findings for Category 2 and 3 testing of opioids for potential abuse deterrence. FDA Public Meeting: Development and regulation of abuse-deterrent formulations of opioid medications. Silver Spring, MD, October 31, 2014.

Henningfield, J.E. Menthol cigarettes and electronic cigarettes: Fact, fiction and policy. First Annual Conference of the Morgan State University Communities Engaged in Advocating for a Smoke Free Environment (CEASE), Baltimore, MD, 21210, November 8, 2014.

Cone, E.J. and Henningfield, J.E. (Split presentation) Methodology and implications of in-vitro testing of abuse deterrent formulations (ADFs) for industry, real world abusers, and the design of human abuse liability studies. Human Abuse Liability and Abuse-Deterrent Formulations Conference. Silver Spring. MD, November 8, 2014.

Nichols, D.E., Johnson, M.W., Griffiths, R.R., and Henningfield, J.E. The path toward making psilocybin available for medical use. American College of Neuropsychopharmacology, Phoenix, AZ, December 10, 2014.

Henningfield, J.E. Electronic nicotine delivery systems: The promise, the peril, and the urgent need for regulation. University of Texas, MD Anderson Cancer Center, Division of Cancer Prevention and Population Sciences, Cancer Control Grand Rounds. Houston, January 16, 2015.

Henningfield, J.E. Continuum of Risk/Harm Reduction: History and lessons from other areas of substance abuse and addiction control. Workshop: Continuum of Risk: Exploring the boundaries of nicotine use and regulation. Society for Research on Nicotine and Tobacco. Philadelphia. February 25, 2015.

Henningfield, J.E. Tribute to Nigel Gray. Plenary Session, Society for Research on Nicotine and Tobacco. Philadelphia. February 25, 2015.

Henningfield, J.E., Cone, E.J., Buchhalter, A.R., Fant, J.G., Gitchell, J.G., and Pinney, J.M. FDA performance standards for electronic nicotine delivery systems: Perspectives from the FDA 2013 Draft Guidance for Abuse-Deterrent Opioids. Society for Research on Nicotine and Tobacco. Philadelphia. February 26, 2015.

Henningfield, J.E. Discussant, Addiction Panel. Electronic Cigarettes and the Public Health: A Public Workshop. Center for Tobacco Products, Food and Drug Administration. Hyattsville, MD, March 9-10, 2015.

Henningfield, J.E. Buprenorphine pharmacology and epidemiology: Conclusions and implications for controlled substance scheduling. Malaysia Association for the Study of Pain. And the National Pharmaceutical Bureau (“FDA”) Division of Pharmacy and Division of Compliance. Update on Controlled Drug Practice Guidance and Policy. The Majestic Hotel, Kuala Lumpur, Malaysia, March 26, 2015.

Henningfield, J.E. Electronic nicotine delivery systems: The promise, the peril, and the urgent need for regulation. Virginia Commonwealth University. Center for the Study of Tobacco Products, Richmond, VA, March 30, 2015.

Henningfield, J.E. Discussant: Approaches to identify and classify adverse events and aberrant behaviors related to abuse, misuse and diversion during clinical drug development. Advances in Abuse Potential Assessments – Building on the FDA Draft Guidance for Industry. Organized by the Cross-Company Abuse Liability Consortium, (C-CALC), with scientific support from the National Institute on Drug Abuse, and presentations by FDA and NIDA representatives. Bethesda, North Marriott, April 16-17, 2015.

Henningfield, J.E. Towards E-Vapor product standards: US Standards. Evidence Based Science and Regulation of the Tobacco and E-Vapor Industries. 100th Annual Meeting and Williamsburg X Conference. Tobacco Manufacturers Association (TMA). Kingsmill Resort & Conference Center, Williamsburg, VA, May 18-20, 2015.

Henningfield, J.E. “Lessons from elsewhere”; what can the vapour industry learn from other sectors? Can a system like the U.S. OTC monographs work for ENDS? Satellite 2: Product Standards - Progress towards standards for nicotine delivery devices. Global Forum on Nicotine, Warsaw, Poland, June 5-6, 2015

Henningfield, J.E. Discussant: A Different Kind of Endgame. What does the science tell us? Global Forum on Nicotine, Warsaw, Poland, June 5-6, 2015.

Henningfield, J.E., Cone, E.J., Buchhalter, A.R., and Fant, R.V. Abuse liability assessment of electronic nicotine delivery systems: Regulatory precedents from the FDA 2015 Guidance for Abuse-Deterrent Opioids: It's All About Response Cost. International Study Group Investigating Drugs as Reinforcers (ISGIDAR). Satellite to the College on Problems of Drug Dependence Annual Meeting. Arizona Biltmore, Phoenix, June 13, 2015.

Cone, E.J., Buchhalter, A.R., Wang, D.W., and Henningfield, J.E. ALERRT™ visual analog scale: Assessing “work” requirements associated with tampering of abuse-deterrent opioid formulations. College on Problems of Drug Dependence Annual Meeting. Arizona Biltmore, Phoenix, June 13-18, 2015.

Henningfield, J.E. Pharmacokinetic and dynamic factors in abuse potential: Historical perspectives from research on opioids, stimulants and nicotine. In Symposium X: The Interplay of pharmacokinetics and pharmacodynamics in abuse potential: Modeling Madness? College on Problems of Drug Dependence Annual Meeting. Arizona Biltmore, Phoenix, June 13-18, 2015.

Henningfield, J.E., Chair and Introduction: New Analgesic and Abuse Deterrent Approaches: Kappa Opioid Receptor Agonists (KORAs). Satellite Symposium to College on Problems of Drug Dependence Annual Meeting. Arizona Biltmore, Phoenix, June 17, 2015.

Dear Representative,

The current ban on kratom in Wisconsin is worrisome to me and my customers; as a seller of natural kratom products this ban prevents many of my customers from being able to buy safe natural kratom products. The ban stops the sale of products containing kratom, a natural botanical from the coffee family, because of the misinformed belief that it is dangerous. As a business owner, my constant goal is to be able to supply customers with safe products that they want to buy. That's why it's frustrating to me that Wisconsin has banned this safe product which I am no longer able to sell in the state. This ban has also closed off my ability to open an additional business location in the badger state where the product used to be very popular.

There are two types of kratom, the natural form of the plant that has been used as a natural pain reliever for centuries, and synthetically spiked kratom that has been marketed as a form of legal high. I sell the safe, natural version, but in an effort to ban the spiked kratom, the ban includes all forms of kratom, including the natural, helpful one I sell.

Capitalizing on the fear that all kratom is bad, and falsely equating it to something that it is not is a dangerous way to legislate. This rush to judgment of a product without sound scientific reasons will affect the ability of consumers to buy goods they want and by limiting consumers' choice of goods you are making it harder for small businesses like mine to survive. Providing Wisconsin customers with natural kratom would help the economy and allow me to do business in the state again.

Synthetically spiked kratom is a dangerous product; one we do not sell, and typically those that do are marketing to people seeking illegal drugs and other ways to get high. The legislature should concentrate its efforts on spiked kratom and dangerous synthetic drugs instead of attacking legitimate business owners for selling safe products like I do.

Any small business owner will tell you, we do not want to sell products that are harmful to our customers, we only want to sell products our customers want to buy, and banning a product because the product is misunderstood is bad policy making. This form of regulation for regulation's sake leads the legislature down a path to ban many safe products just because someone doesn't understand the scientific name of an ingredient.

Many consumers find these safe, natural products beneficial and reversing the current ban would allow me to expand into Wisconsin and help the economy.

Sincerely,

A handwritten signature in black ink that reads "Joe Marino". The signature is written in a cursive, flowing style.

Joseph Marino
Green Leaf Kratom
Browns Mills, New Jersey

Dear legislators and regulators,

I strongly urge you to support repealing the ban on the safe herb *Mitragyna speciosa* or kratom as it is more commonly known. As a lawmaker, I understand it is your duty to protect the safety of our citizens, however, the current prohibition was put in place without considering all of the facts.

In 2014, the Wisconsin State Legislature passed a law banning the two naturally occurring alkaloids in kratom, 7-hydroxymitragynine and mitragynine. The sponsors of the legislation in 2014 cite the rise in synthetic drug use in Wisconsin as their motivation. However, they missed a very important piece of information.

Kratom is a naturally-occurring plant. The naturally-occurring herb has been used as a safe and effective natural pain reliever and mood booster for centuries. Today, millions of Americans safely use it today for the same reason as a natural form of relief for chronic pain sufferers and even for veterans suffering from PTSD.

Across the country naturally occurring Kratom products in the form of leaves that can be steeped in tea or chewed, capsules and beverages are being sold across the country in stores. However, not in Wisconsin. As the owner of a staffing company, the arbitrary ban on substances like kratom could affect my business and the future on my clients. It concerns me that businesses will have to become more stringent on the use of completely safe substances by their employees. Overnight I could be attempting to place someone in a job that is unknowingly using an illegal substance. I once thought it was above my pay grade to dive that deeply into the personal lives of my clients, questioning them on their personal use of natural pain relievers, but am now increasingly being forced to ask uncomfortable questions that have no relation to job qualifications.

In addition, placing those willing to work in good jobs requires a healthy economy. Banning substances like kratom can only hurt the employment picture in the state. Job opportunities at convenience stores, service stations, health food stores, and other mid-level, "blue collar" jobs go away when businesses are sued and forced to shut down over a substance they have never even heard of before. Overturning the current ban in Wisconsin would help business owners and job seekers in the state.

Naturally-occurring Kratom is not a synthetic drug, it's not even a drug. Unfortunately, as just about any plant, chemical or substance, it can be chemically adulterated. Synthetically modified, adulterated, or "spiked" kratom can be a dangerous substance and may be a public health concern. But natural and adulterated Kratom are two very different things and banning a product because the product is misunderstood is bad policy making. This reactive mode of over-regulation leads our state down a path where many more safe products may be banned as legislators hastily seek to quell misguided public opinion.

Legislators' lack of chemistry and scientific understanding shouldn't be the reason customers in Wisconsin don't have access to the natural, safe products.

The kratom ban was enacted in haste in response to misinformed, overblown media reports. Wisconsin residents deserve the free choice to decide what products help their ailments. The safe and effective kratom herb is a legitimate and natural choice that does not cause dependency. As you consider ways to help small businesses, seniors, veterans, and chronic pain sufferers in Wisconsin, I strongly urge you to reverse the ban on a safe substance that is currently used responsibly within the law by residents of the vast majority of states across the country.

Sincerely,

Rick Richard

A handwritten signature in blue ink that reads "Rick Richard". The signature is written in a cursive, slightly slanted style.

Janesville, WI

July 28, 2015

Dear Wisconsin Controlled Substances Board:

I am a teacher from Madison, Wisconsin. Three years ago I was bit by a tick. I suffered a strange, flu-like illness and experienced facial paralysis. The doctors were not sure if it was Lyme, but they gave me two weeks of antibiotics and performed surgery on my face. After that initial treatment, I felt better for a month or so. However, I became sick again, including new symptoms of bone crushing fatigue, tinnitus, neuropathy, dizziness and brain fog. I have been seeing doctors ever since, but none have been able to really help me.

I have been diagnosed with all the usual Lyme misdiagnoses; fibromyalgia, neuropathy, chronic fatigue syndrome, thyroiditis, etc. Two years ago, I had a new Lyme test called an Ispot, which has been approved by the CDC. I was tested and was still positive for Lyme and again began receiving treatment that my doctor prescribed. After two years, some things were only slightly better.

While visiting a friend down south I was introduced to kratom. It is the first thing I have tried that gives me energy, motivation and relieves my many symptoms. I had a doctor suggest I drink coffee to deal with the fatigue. However, coffee makes me shake and gives me heart palpitations. Kratom also helps with my pain and helps me sleep.

Kratom is so gentle and effective, and it's natural. No chemicals, no harsh side effects. I feel almost normal after I take just half of a teaspoon. I think God has given me something to help me on my path to healing. Until very recently, I did not know it was illegal in Wisconsin. I don't understand why God would give us something so effective and safe, but lawmakers would take it away.

Please look at the research and history of this herb. Please let those of us with chronic illness continue to use this life-saving botanical.

Thank you.

SBT
Madison, Wisconsin

August 3, 2015

Dear Controlled Substances Board:

For the past 34 years, I have suffered from chronic pain. It started with tension and migraine headaches, and over the years has spread into my neck, shoulders and back. In 1994 I was diagnosed with fibromyalgia and cystic fibrosis. The pain and fatigue has significantly affected my day-to-day routine and the quality of my life. In 1998, the pain became so overwhelming I had to stop working.

In 2009, my condition worsened after falling ill. I became severely depressed and began having panic attacks. My doctors have prescribed me nearly every class of antidepressants. None of them really helped, and the side effects with many of them were unbearable.

After decades of ineffective prescriptions and pain therapies, I was desperate for pain relief. I first learned of kratom in November 2014, and shortly thereafter placed my first order on Amazon. At the time, I did not know that it was illegal in Wisconsin. After trying it, there was a remarkable difference in my pain, mood and energy.

Kratom has changed my life. It helps me with my mood, and I can honestly say I am no longer depressed. It helps me with energy, and I actually feel like doing things rather than staying in bed all day. It helps so much with the chronic pain that I hardly ever take my prescribed pain-killers (opiates).

I have been proud to call Western Wisconsin home for most of the last 46 years. That changed when my state banned something that's made such a positive impact on my life. Kratom is natural, safe and it's helping me and thousands like me. Please reverse the ban on kratom in Wisconsin.

A believer.

S.H.
Western Wisconsin

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 8/14/15	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? NGA Policy Academy Review - Discussion and Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: For the Board's consideration, attached is the executive summary of recommendations developed during the State's participation in the National Governors Association Policy Academy on Reducing Prescription Drug Abuse.			

Wisconsin Executive Summary

Mission Statement

To reduce prescription drug misuse, abuse, and diversion through a patient/family centered, data-driven, collaborative, multi-disciplinary approach that ensures adequate access for those with medical need.

Core Area #1: Public policy initiatives

Goal #1: Identify strategies to ensure adequate supply of naloxone

- Identify best practices in other states
- Determine most viable options to implement in Wisconsin
- Work with Governor and Legislature to implement the policy

Goal #2: Expand “good Samaritan” immunity to overdose patients

- Work with Governor and Legislature to implement the policy

Goal #3: Communicate with state and federal legislators regarding prescription drug-related legislation

- Monitor state and federal proposals regarding the following topics:
 - Targeted mandatory use of PDMPs
 - Mandatory continuing education requirements for prescribers of controlled substances
 - Pain as the fifth vital sign and requirements to use the pain scale

Core Area #2: Strategic criminal enforcement

Goal #1: Conduct training on the identification and investigation of cases related to prescription drug abuse

- Work with the U.S. Attorney’s Office, the Drug Enforcement Administration and others to develop and conduct six prescription drug abuse trainings around Wisconsin

Goal #2: Increase law enforcement awareness and use of the PDMP

- Work with DSPS to offer PDMP training to law enforcement officers around Wisconsin

Goal #3: Interface the PDMP with the Crime Alert Network

- Work with the Department of Safety and Professional Services to develop a communications interface between the PDMP and Crime Alert Network

Core Area #3: PDMP and public health data

Goal #1: Create a PDMP oversight body with a wide-ranging perspective

- Work with the Governor and Legislature to transfer oversight of the PDMP to the Wisconsin Controlled Substances Board
- Change the membership of the Controlled Substances Board to include a physician, nurse, and dentist in addition to representatives from the Department of Justice and Department of Health Services

Goal #2: Improve the usability and efficiency of the PDMP

- Continue projects to integrate PDMP data into electronic medical records software
- Improve the PDMP web portal to decrease the number of pages and clicks required to obtain data
- Improve the PDMP web portal to give prescribers data that compares their prescribing practices to similarly situated prescribers
- Work with the Governor and Legislature to decrease the reporting interval from 7-days to 24-hours
- Work with the Board overseeing the PDMP to expand access to non-prescribing health professionals such as NPs, medical directors, and support staff
- Improve the PDMP alert features to create more persistent “notes” on patient reports and include more types of alerts

Goal #3: Improve the availability of PDMP data for public health purposes

- Continue to create the PDMP Public Health Portal
- Work with the Department of Health Services to improve PDMP data quality
- Integrate PDMP data into existing public health data sources

Core Area #4: Substance abuse treatment

Goal #1: Establish non-methadone Opioid Treatment Programs

- Establish three opioid treatment programs in rural, underserved and high need areas of the state with associated funding to provide outpatient care, stabilization services, detoxification services and medication-assisted treatment services

Goal #2: Promote treatment best practices

- Establish at least two statewide training events for substance abuse counselors and clinicians regarding delivery of evidence-based treatment practices for individuals seeking treatment for opioid dependence
- Establish at least two statewide training events for physicians and allied health professionals to recruit more physicians to offer buprenorphine management services for individuals who are opioid dependent

Goal #3: Assure access to treatment on demand

- Work with State leadership and members of the Legislature to examine the current substance abuse treatment system and develop recommendations for greater funding flexibility to assure access to treatment on demand
- Expand regional service models through the Mental Health and Substance Abuse Regional Pilot Project

Core Area #5: Public education campaign

Goal #1: Develop a multi-faceted campaign about prescription drug safety

- Work with the Department of Health Services, Department of Justice, private stakeholders, and an advertising agency to create a statewide multimedia campaign about prescription drug safety that includes direct-to-consumer marketing and prescriber education components
- Launch campaign with press releases and spokespersons
- Develop criteria to monitor the effectiveness of the campaign over time

**State of Wisconsin
Department of Safety & Professional Services**

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3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 8/14/15	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? NASCSA Annual Conference– Travel Request	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: <p>For the Board’s consideration, the Annual Conference of the National Association of State Controlled Substances Authorities (NASCSA) is in October. The draft agenda is attached. The Board may consider designating a member to attend.</p>			

NASCSA CONFERENCE PROGRAM
OCTOBER 20-23, 2015
Hotel Valley Ho
Scottsdale, Arizona

Monday, Oct. 19, 2015

3-5 p.m. – Registration Desk Open

4 p.m. – 6 p.m. – NASCSA Executive Committee (open to all)

Tuesday, Oct. 20, 2015

9 a.m. – 4:30 p.m. - Registration Desk Open

9 – 11:30 a.m. – Prescription Monitoring Program Roundtable Sessions

- **9 - 10 a.m. Facilitated Discussion With PMP Administrators – Recent NASCSA Survey**
 - Sherry Green, NASCSA Consultant
- **10 – 10:10 a.m. – Break**
- **10:10 – 11 a.m. – Continued Discussion**
- **11 - 11:30 a.m. - Presentation: Highlights from NASCSA’s PMP Grant Awardee**
 - David Dryden, Delaware Board of Pharmacy

1 -1:30 p.m. - NASCSA Business Session/Opening Comments

- Karen Tannert, Chair, NASCSA Executive Committee, Texas Department of Health
- Ralph Orr, President, NASCSA, Prescription Drug Monitoring Program, Virginia Department of Health Professions

1:30 – 2:30 p.m. – Legislative & Regulatory Update

- John Gilbert, Hyman, Phelps & McNamara

2:30 – 3:15 p.m. – Office of National Drug Control Policy Update

- Mary Lou Leary, Deputy Director of State and Local Affairs, Office of National Drug Control Policy

3:15 – 3:30 p.m. – Break

3:30 – 4:40 p.m. – Update from the Substance Abuse Mental Health Services Administration

- Jinhee Lee, PharmD, Division of Pharmacologic Therapies, Center for Substance Abuse Treatment (CSAT), Substance Abuse Mental Health Services Administration

6 – 8:30 p.m. - NASCSA Reception (included)

Wednesday, Oct. 21, 2015

7-8 a.m. – Continental Breakfast

7:30 – noon - Registration Desk Open

8:30 – 9:30 a.m. – Developing a Five-Year Roadmap – The Pew Charitable Trust

- Cynthia Reilly, Director, Prescription Drug Abuse Project, The Pew Charitable Trusts
- Bureau of Justice Assistance - TBA

9:30 – 10:30 a.m. – “A Nation in Pain”

- Jo-Ellen Abou-Nader, Express Scripts

10:30 – 10:45 a.m. - Break

10:45 a.m. – noon – Update from the Drug Enforcement Administration

- Ruth Carter, Drug Enforcement Administration, Office of Diversion Control

NASCSA CONFERENCE PROGRAM
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Noon – 1:30 p.m. – Lunch (on your own)

Barbara Carter, Minnesota Board of Pharmacy

1:30 – 2:45 p.m. – Prescription Drug Abuse by Health Care Professionals

- Kathy Simpson, Executive Director, Pennsylvania Nurses Peer Assistance Program
- David Greenberg, MD, Arizona Medical Board
- Elaine Hugunin, Executive Director, Arizona Board of Dental Examiners Representative

2:45 – 3 p.m. – Break

3 -4:30 p.m. – Medical Marijuana: Implications for Law Enforcement and Regulatory Agencies

- Jo McGuire, Smart Approaches to Marijuana (SAM), Colorado
- Sheila Polk, County Attorney for Yavapai County
- John Gadea, Connecticut Drug Control Division

4:30 -5 p.m. – Business Meeting (continued)

5-6:30 p.m. – Hospitality Room Open

Thursday, Oct. 22, 2015

7-8 a.m. – Continental Breakfast

8 – 10:15 a.m. Concurrent Workshops –

Attendees choose 2 out of 3 workshops to attend. Note: seating may be limited to accommodate space considerations

1. Workshop 1 – Hot Topics for Prescription Monitoring Programs

Facilitators:

*Dana Crenshaw, Mississippi Board of Pharmacy
Kathy Zahn, North Dakota Board of Pharmacy*

2. Workshop 2 – The Drug Supply Security Act

- Martha Russell, Director of Corporate Regulatory Affairs, Cardinal Health

3. Workshop 3 – State Responses to the Prescription Drug Abuse and Heroin Crisis

Facilitators:

- Ralph Orr, Virginia Board of Pharmacy
- Joshua S. Vinciguerra, New York Bureau of Narcotic Enforcement
- Chad Zadrazil, Wisconsin Prescription Drug Monitoring Program

10:15 – 10:30 a.m. – Break

10:30 a.m. – noon – National Drug Trends and Investigations

- Alan McGill, Supervisory Narcotics Agent, Pennsylvania Office of the Attorney General
- Timothy Dewey, New York Bureau of Narcotics

11:45 – 12:45 p.m. – NASCSA Networking Luncheon (included)

12:45 – 1:30 p.m. – Novel Psychoactive Substances and Other Emerging Issues in Substance Abuse

- James Hall, Epidemiologist, Center for Applied Research on Substance Use and Health Disparities, Nova Southeastern University

1:30-2:30 p.m. – Abuse Deterrent Formulations: Has it Made a Difference?

NASCSA CONFERENCE PROGRAM
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- Douglas Throckmorton, Deputy Director, CDER, US Food & Drug Administration (invited)

2:30 – 3 p.m. – Presentation of NASCSA “White Paper” on Pseudoephedrine –

- Trish Rippetoe Freeman, RPh, PhD, University of Kentucky College of Pharmacy

3 – 3:45 p.m. Electronic Prescribing and Its Impact on Prescribing of Controlled Substances

- Timothy Dewey, New York Bureau of Narcotics

3:30 – 3:45 p.m. - Break

3:45 - 5 p.m. Business Meeting (continued)

- Ralph Orr, President, NASCSA

5-6:30 p.m. – Hospitality Room Open

Friday, Oct. 23, 2015

7:30-8 a.m. – Full Breakfast

8-9 a.m. Business Meeting (continued)

- Ralph Orr, President, NASCSA

9 - 10 a.m. – PMP Data Integration Into Health IT Systems

- Craig Berberet, Illinois Department of Health
- Chad Garner, Ohio Board of Pharmacy
- Dean Wright, Arizona Board of Pharmacy
- Chad Zadrazil, Wisconsin Department of Safety & Professional Services

10-11 a.m. – "Chemical Dependence in the New Millennium: From Jail Cells to Brain Cells"

- Mark Menestrina, MD

11 a.m. – noon – By-Products of Regulation: The Law of Unintended Consequences

- Bruce Matthews, Simplifico Inc.

Noon – 12:15 p.m. - Closing Remarks

NOTE: Agendas for Business Meetings will be available in the conference notebook

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 8/14/15	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Acetyl Fentanyl Federal Scheduling– Informational	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: For the Board’s information, attached is information from the DEA regarding the temporary scheduling of Acetyl Fentanyl into Schedule I. Acetyl Fentanyl is already Schedule I in Wisconsin.			



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Rules - 2015

[Federal Register Volume 80, Number 137 (Friday, July 17, 2015)]
 [Rules and Regulations]
 [Pages 42381-42385]
 From the Federal Register Online via the Government Publishing Office [www.gpo.gov]
 [FR Doc No: 2015-17563]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-413F]

Schedules of Controlled Substances: Temporary Placement of Acetyl Fentanyl Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this final order to temporarily schedule the synthetic opioid, N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl), and its optical, positional, and geometric isomers, salts and salts of isomers, into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of this opioid substance into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, import, export, engage in research, or possess), or propose to handle, acetyl fentanyl.

DATES: This final order is effective on July 17, 2015.

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. **21 U.S.C. 801-971**. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

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

Section 201 of the CSA, **21 U.S.C. 811**, provides the Attorney General with the authority to temporarily place a

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

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

Background

Section 201(h)(4) of the CSA, **21 U.S.C. 811(h)(4)**, requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of the Administrator's intention to temporarily place a substance into schedule I of the CSA. The Administrator transmitted the notice of intent to place acetyl fentanyl into schedule I on a temporary basis to the Assistant Secretary by letter dated April 7, 2015. The Assistant Secretary responded to this notice by letter dated April 29, 2015 (received by the DEA on May 05, 2015), and advised that based on review by the FDA, there are currently no investigational new drug applications or approved new drug applications for acetyl fentanyl. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of acetyl fentanyl into schedule I of the CSA. The DEA has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). Acetyl fentanyl is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for acetyl fentanyl under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the scheduling of acetyl fentanyl in schedule I on a temporary basis is necessary to avoid an imminent hazard to public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule acetyl fentanyl was published in the Federal Register on May 21, 2015. 80 FR 29227.

[1] Because the Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations, for purposes of this final order, all subsequent references to "Secretary" have been replaced with "Assistant Secretary." As set forth in a memorandum of understanding entered into by HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Assistant Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985.

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

A substance meeting the statutory requirements for temporary scheduling may only be placed into schedule I, **21 U.S.C. 811(h)(1)**. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. **21 U.S.C. 812(b)(1)**. Available data and information for acetyl fentanyl, summarized below, indicate that this synthetic opioid has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA analysis is available in its entirety under the tab "Supporting and Related Material" of the public docket of this action at www.regulations.gov under Docket Number DEA-413F.

Factor 4. History and Current Pattern of Abuse

Clandestinely produced substances structurally related to the schedule II opioid analgesic fentanyl were trafficked and abused on the West Coast in the late 1970s and 1980s. These clandestinely produced fentanyl-like substances were commonly known as designer drugs, and recently, there has been a reemergence in the trafficking and abuse of designer drug substances, including fentanyl-like substances. Alpha-methylfentanyl, the first fentanyl analogue identified in California, was placed into schedule I of the CSA in September 1981. Following the control of alpha-methylfentanyl, the DEA identified several other fentanyl analogues (3-methylthiofentanyl, acetyl-alpha-methylfentanyl, beta-hydroxy-3-methylfentanyl, alpha-methylthiofentanyl, thiofentanyl, beta-hydroxyfentanyl, para-fluorofentanyl and 3-methylfentanyl) in submissions to forensic laboratories. These substances were temporarily controlled under schedule I of the CSA after finding that they posed an imminent hazard to public safety and were subsequently permanently placed into schedule I of the CSA.

The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by State and local forensic laboratories across the country. The first laboratory submission of acetyl fentanyl was recorded in Maine in April 2013 according to NFLIS. NFLIS registered eight reports containing acetyl fentanyl in 2013 in Louisiana, Maine, and North Dakota; and 30 reports in 2014 in Florida, Illinois, Louisiana, Maine, New Jersey, Ohio, Oregon, Pennsylvania, and Virginia.

The System to Retrieve Information from Drug Evidence (STRIDE) is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from this database are from the DEA, other Federal agencies, and some local law enforcement agencies. Acetyl fentanyl was first reported to STRIDE in September 2013 from exhibits obtained through a controlled purchase in Louisiana. In October 2013, an exhibit collected from a controlled purchase of suspected oxycodone tablets in Rhode Island contained acetyl fentanyl as the primary substance. In 2014, STARLiMS (a Web-based, commercial laboratory information management system that is in transition to replace STRIDE) and STRIDE reported eight additional seizures in Colorado, Florida, Georgia, and Washington.

In August 2013, the Centers for Disease Control and Prevention published an article in its Morbidity and Mortality Weekly Report documenting a series of 14 fatalities related to acetyl fentanyl that occurred between March and May 2013. In December 2013, another fatality associated with acetyl fentanyl was reported in Rhode Island for a total of 15 fatalities. In February 2014, the North Carolina Department of Health and Human Services issued a health advisory related to acetyl fentanyl following at least three deaths related to this synthetic drug. Toxicologists at the North Carolina Office of the Chief Medical Examiner detected acetyl fentanyl in specimens associated with deaths that occurred in January 2014 in Sampson, Person, and

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Transylvania counties. In July and August 2014, four additional fatalities involving acetyl fentanyl were reported for a total of seven fatalities in North Carolina. Deaths involving acetyl fentanyl have also been reported in California (1), Louisiana (14), Oregon (1) and Pennsylvania (1).

A significant seizure of acetyl fentanyl occurred in April 2013 during a law enforcement investigation in Montreal, Canada. Approximately three kilograms of acetyl fentanyl in powder form and approximately 11,000 tablets containing acetyl fentanyl were seized. Given that a typical dose of acetyl fentanyl is in the microgram range, a three kilogram quantity could potentially produce millions of dosage units. In the United States, tablets that mimic pharmaceutical opioid products have been reported in multiple states, including Colorado, Florida, Georgia, Rhode Island, and Washington. Recent reports indicate that acetyl fentanyl in powder form is available over the Internet and has been imported to addresses within the United States.

Evidence also suggests that the pattern of abuse of fentanyl analogues, including acetyl fentanyl, parallels that of heroin and prescription opioid analgesics. For example, seizures of acetyl fentanyl have been encountered both in powder and in tablet form. It is also known to have caused many fatal overdoses, in which intravenous routes of administration and histories of drug abuse are documented.

Factor 5. Scope, Duration and Significance of Abuse

The DEA is currently aware of at least 39 fatalities associated with acetyl fentanyl. These deaths occurred in 2013 and 2014 from six states including California, Louisiana, North Carolina, Oregon, Pennsylvania, and Rhode Island. STARLiMS and STRIDE, databases capturing drug evidence information from DEA forensic laboratories, have a total of 10 drug reports in which acetyl fentanyl was identified in six cases for analyzed drugs submitted from January 2010--December 2014 from Colorado, Florida, Georgia, Louisiana, Rhode Island, and Washington. It is likely that the prevalence of acetyl fentanyl in opioid analgesic-related emergency room admissions and deaths is underreported since standard immunoassays cannot differentiate acetyl fentanyl from fentanyl.

The population likely to abuse acetyl fentanyl overlaps with the populations abusing prescription opioid analgesics and heroin. This is evidenced by the routes of administration and drug use history documented in acetyl fentanyl fatal overdose cases. Because abusers of acetyl fentanyl are likely to obtain the drug through illicit sources, the identity, purity, and quantity is uncertain and inconsistent, thus posing significant adverse health risks to its abusers. This risk is particularly heightened by the fact that acetyl fentanyl is a highly potent opioid (15.7 fold more potent than that of morphine as tested in mice using an acetic acid writhing method). Thus small changes in the amount and purity of the substance could potentially lead to overdose and death.

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

Acetyl fentanyl exhibits a pharmacological profile similar to that of fentanyl and other opioid analgesic compounds, and it is a potent opioid analgesic reported to be 1/3 as potent as fentanyl and 15.7 times as potent as morphine in mice tested in an acetic acid writhing method. In addition, studies also showed that the range between the effective dose (ED50) and the lethal dose (LD50) of acetyl fentanyl is narrower than that of morphine and fentanyl, increasing the risk of fatal overdose. Thus, its abuse is likely to pose quantitatively greater risks to the public health and safety than abuse of traditional opioid analgesics such as morphine.

Based on the above pharmacological data, the abuse of acetyl fentanyl at least leads to the same qualitative public health risks as heroin, fentanyl, and other opioid analgesic compounds. The public health risks attendant to the abuse of heroin and opioid analgesics are well established. The abuse of opioid analgesics has resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses.

Acetyl fentanyl has been associated with numerous fatalities. At least 39 overdose deaths due to acetyl fentanyl abuse have been reported in six states in 2013 and 2014, California, Louisiana, North Carolina, Oregon, Pennsylvania, and Rhode Island. This indicates that acetyl fentanyl poses an imminent hazard to public safety.

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

Based on the data and information summarized above, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of acetyl fentanyl poses an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for this substance in the United States. A substance meeting the statutory requirements for temporary scheduling, **21 U.S.C. 811(h)(1)**, may only be placed into schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for acetyl fentanyl indicate that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, through a letter dated April 7, 2015, notified the Assistant Secretary of the DEA's intention to temporarily place this substance into schedule I.

Conclusion

In accordance with the provisions of section 201(h) of the CSA, **21 U.S.C. 811(h)**, the Administrator considered available data and information, herein sets forth the grounds for his determination that it is necessary to temporarily schedule N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl), into schedule I

of the CSA, and finds that placement of this synthetic opioid into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. Because the Administrator hereby finds it necessary to temporarily place this synthetic opioid into schedule I to avoid an imminent hazard to the public safety, this final order temporarily scheduling acetyl fentanyl will be effective on the date of publication in the Federal Register, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2).

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with **21 U.S.C. 811(a)** are subject to formal rulemaking procedures done "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. **21 U.S.C. 877**. Temporary

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scheduling orders are not subject to judicial review. **21 U.S.C. 811(h)(6)**.

Requirements for Handling

Upon the effective date of this final order, acetyl fentanyl will become subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, exportation, research, conduct of instructional activities, and possession of schedule I controlled substances including the following:

1. **Registration.** Any person who handles (manufactures, distributes, imports, exports, engages in research, conducts instructional activities with, or possesses), or who desires to handle, acetyl fentanyl must be registered with the DEA to conduct such activities pursuant to **21 U.S.C. 822, 823, 957, and 958** and in accordance with **21 CFR parts 1301 and 1312**, as of July 17, 2015. Any person who currently handles acetyl fentanyl, and is not registered with the DEA, must submit an application for registration and may not continue to handle acetyl fentanyl as of July 17, 2015, unless the DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of this substance in a manner not authorized by the CSA on or after July 17, 2015 is unlawful and those in possession of any quantity of this substance may be subject to prosecution pursuant to the CSA.

2. **Security.** Acetyl fentanyl is subject to schedule I security requirements and must be handled and stored pursuant to **21 U.S.C. 821, 823, 871(b)**, and in accordance with **21 CFR 1301.71-1301.93**, as of July 17, 2015.

3. **Labeling and packaging.** All labels, labeling, and packaging for commercial containers of acetyl fentanyl must be in compliance with **21 U.S.C. 825, 958(e)**, and be in accordance with **21 CFR part 1302** as of July 17, 2015. Current DEA registrants shall have 30 calendar days from July 17, 2015, to comply with all labeling and packaging requirements.

4. **Inventory.** Every DEA registrant who possesses any quantity of acetyl fentanyl on the effective date of this order must take an inventory of all stocks of this substance on hand as of July 17, 2015, pursuant to **21 U.S.C. 827 and 958**, and in accordance with **21 CFR 1304.03, 1304.04, and 1304.11(a)** and (d). Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including acetyl fentanyl) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

5. **Records.** All DEA registrants must maintain records with respect to acetyl fentanyl pursuant to **21 U.S.C. 827 and 958**, and in accordance with **21 CFR parts 1304, 1307, and 1312** as of July 17, 2015. Current DEA registrants authorized to handle acetyl fentanyl shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

6. **Reports.** All DEA registrants who manufacture or distribute acetyl fentanyl must submit reports pursuant to **21 U.S.C. 827** and in accordance with **21 CFR parts 1304, 1307, and 1312** as of July 17, 2015.

7. **Order Forms.** All DEA registrants who distribute acetyl fentanyl must comply with order form requirements pursuant to **21 U.S.C. 828** and in accordance with **21 CFR part 1305** as of July 17, 2015.

8. **Importation and Exportation.** All importation and exportation of acetyl fentanyl must be in compliance with **21 U.S.C. 952, 953, 957, 958**, and in accordance with **21 CFR part 1312** as of July 17, 2015.

9. **Quota.** Only DEA registered manufacturers may manufacture acetyl fentanyl in accordance with a quota assigned pursuant to **21 U.S.C. 826** and in accordance with **21 CFR part 1303** as of July 17, 2015.

10. **Liability.** Any activity involving acetyl fentanyl not authorized by, or in violation of the CSA, occurring as of July 17, 2015, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

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

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

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

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

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

Pursuant to the Congressional Review Act, "any rule for which an agency for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the Federal agency promulgating the rule determines." 5 U.S.C. 808(2). It is in the public interest to schedule these substances immediately because they pose a public health risk. This temporary scheduling action is taken pursuant to **21 U.S.C. 811(h)**, which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h) exempts the temporary scheduling order

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from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie **21 U.S.C. 811(h)**, that is, the DEA's need to move quickly to place this substance into schedule I because it poses an imminent hazard to public safety, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, in accordance with 5 U.S.C. 808(2), this order shall take effect immediately upon its publication.

List of Subjects in 21 CFR Part 1308

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

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

PART 1308--SCHEDULES OF CONTROLLED SUBSTANCES

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

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

- 2. Amend **Sec. 1308.11** by adding paragraph (h)(24) to read as follows:

Sec. 1308.11 Schedule I.

(h)***

(24) N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: acetyl fentanyl)—(9821)

Dated: July 13, 2015.

Chuck Rosenberg,
Acting Administrator.

[FR Doc. 2015-17563 Filed 7-16-15; 8:45 am]

BILLING CODE 4410-09-P

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**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Chad Zadrazil and Andrea Magermans		2) Date When Request Submitted: Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WISCONSIN CONTROLLED SUBSTANCES BOARD			
4) Meeting Date: 8/14/15	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Drug Overdose WPR Story– Informational	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: For the Board’s information, attached is an article that describes drug overdose as the leading cause of injury in Wisconsin.			



Published on *Wisconsin Public Radio* (<http://www.wpr.org>)

[Home](#) > Drug Overdoses Now Leading Cause Of Injury In Wisconsin, Report Says



Drug Overdoses Now Leading Cause Of Injury In Wisconsin, Report Says

Report: Overdoses Surpass Car Crashes In Most States

By Shamane Mills

Updated:

Thursday, June 18, 2015, 10:37am

Drug overdoses have become the leading cause of injury in 36 states, including Wisconsin, according to a national report.

The Trust for America's Health has issued the report that drug overdoses have now surpassed motor vehicle-related deaths in most states.

Jeffrey Levi, the group's executive director, said that drug abuse can have a cascading effect on people's health.

“The overdose problem is not just related to prescription drugs, but where it leads, which is use of heroin and other injectable drugs, which then results in not just the threat of overdose deaths, but also outbreaks of Hepatitis C and HIV,” said Levi

According to the report, Wisconsin has the 29th-highest rate of overdose deaths using a three-year average from 2011 to 2013.

A state law passed last year gives all emergency responders the ability to be trained to administer Naloxone, a drug used to counteract overdoses.

Wisconsin also has a prescription drug monitoring program in which doctors, pharmacists and police can use to track drug purchases.

The report said that 25 states require use of the monitoring program, but Wisconsin doesn't.

Officials with the Department of Safety and Professional Services, the agency that oversees the Prescription Drug Monitoring Program (PDMP), said they have reduced "doctor shopping," which occurs when a patient obtains prescriptions from four or more prescribers and four or more dispensers per calendar month. The PDMP has shown an average decrease of 26 percent per month in doctor shopping since its implementation in 2013.

The Trust for America's report is called "[The Facts Hurt](#) [1]." It looks at 10 injury-prevention factors. These include drug monitoring programs, use of seat belts and ignition locks to prevent drunken driving. Currently, ignition interlock devices are required for all repeat OWI offenders and first-time offenders with a blood alcohol content of 0.15 and above.

Source URL: <http://www.wpr.org/drug-overdoses-now-leading-cause-injury-wisconsin-report-says>

Links

[1] <http://www.healthyamericans.org/reports/injuryprevention15/>