



STATE OF WISCONSIN

Department of Safety and Professional Services

1400 E Washington Ave.

Madison WI 53703

Governor Scott Walker

Secretary Dave Ross

Mail to:
PO Box 8935
Madison WI 53708-8935

Email: dsps@wisconsin.gov
Web: <http://dsps.wi.gov>

Voice: 608-266-2112 • FAX: 608-267-3816 • TTY: 608-267-2416

CONTROLLED SUBSTANCES BOARD

Contact: Dan Williams (608) 266-2112

Room 121A, 1400 E. Washington Avenue, Madison

DECEMBER 11, 2012

Notice: *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.*

FULL BOARD MEETING

12:00 P.M.

OPEN SESSION - CALL TO ORDER – ROLL CALL

- A. **Approval of Agenda**
- B. **Approval of Meeting Minutes of February 27, 2012 (5-8)**
- C. **Approval of Meeting Minutes of September 21, 2012 (9-10)**
- D. Secretary Matters
- E. Administrative Matters
 - 1) 2013 Meeting Dates **(11-12)**
- F. **APPEARANCE 12:10 P.M. – Chad Zadrazil - Prescription Drug Monitoring Program Update (13-16)**
 - 1) Legislative Review of Proposed PDMP Rules
 - 2) Vendor Procurement/RFP Process
- G. **Discussion and Consideration of Alan Bloom Inquiry (17-18)**
- H. **Discussion and Consideration of Eau Claire Police Department Inquiry (19-20)**
- I. **Discussion and Consideration of a Motion Related to Delegating Authority to the SUA Liaisons/Reviewers and the Extent of that Authority; a Discussion, Board-Approval, or Motion Related to Euthanasia Injection Courses (21-24)**
- J. **Discussion and Consideration of CSB 3 (25-28)**
- K. **Discussion and Consideration of Scope Statement as to the Emergency Scheduling of Controlled Substances (29-70)**

- L. **Report on Presentation at the Wisconsin Federated Humane Societies Badger States Conference (71-72)**
- M. **Discussion and Consideration of JAVMA Article Regarding Veterinary Mobile Practice (73-76)**
- N. Items Received After Printing 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 Proposed Final Decision and Order(s)
 - 5) Informational Item(s)
 - 6) Division of Legal Services and Compliance (DLSC) Matters
 - 7) Education and Examination Matters
 - 8) Credentialing Matters
 - 9) Class 1 Hearings
 - 10) Practice Questions/Issues
 - 11) Legislation/Administrative Rule Matters
 - 12) Speaking Engagement(s), Travel, or Public Relation Request(s)
- O. Informational Item(s)
- P. New Business
- Q. Public Comments

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1) (a), Stats.; consider closing disciplinary investigation with administrative warning (s. 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.)

- R. Deliberation of Proposed Stipulations, Final Decisions and Orders including any received after printing of the agenda
- S. Deliberation of Items Received After Printing of the Agenda:
 - 1) Deliberation on Class 1 Hearings
 - 2) Application Issues and/or Reviews
 - 3) Professional Assistance Procedure (PAP)
 - 4) Monitoring Matters
 - 5) Proposed Stipulations, Final Decisions and Orders
 - 6) Administrative Warnings
 - 7) Review of Administrative Warning
 - 8) Orders Fixing Costs/Matters Related to Costs
 - 9) Proposed Final Decisions and Orders
 - 10) Petitions for Summary Suspension
 - 11) Petitions for Re-hearings
 - 12) Education and Examination Matters
 - 13) Credential Issues
 - 14) Supervisor Approvals
 - 15) Appearances from Requests Received or Renewed
 - 16) Motions

T. Division of Legal Services and Compliance

- 1) Case Status Report
- 2) Case Closings

U. Legal Counsel Matters

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

V. Other Board Business

ADJOURNMENT

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**CONTROLLED SUBSTANCES BOARD
MINUTES
FEBRUARY 27, 2012**

PRESENT: Yvonne Bellay, DVM; Alan Bloom; Timothy Boehmer, R.Ph.; Doug Englebert, R. Ph.; Martin Koch

STAFF: Dan Williams, Executive Director; Lydia Thompson, Legal Counsel; Karen Rude-Evans, Bureau Assistant; other DSPS staff

GUESTS: Jay O'Neil, Dane County Sheriff's Office

CALL TO ORDER

Doug Englebert, Chair, called the meeting to order at 1:00 p.m. A quorum of five (5) members was confirmed.

ADOPTION OF AGENDA

Amendments:

- Item L (closed session) – Review of SUA Application(s) – This item is moved to open session after Item E

MOTION: Timothy Boehmer moved, seconded by Yvonne Bellay, to adopt the agenda as amended. Motion carried unanimously.

**PUBLIC HEARING ON CSB 3 RELATING TO
SPECIAL USE AUTHORIZATIONS**

Chair Doug Englebert called the public hearing to order at 1:02 p.m. No speakers registered to present testimony. Mr. Englebert adjourned the hearing at 1:04 p.m.

Consideration Of and Responses to Comments on CSB 3 From the Legislative Clearinghouse and From the Public

The Board reviewed the Clearinghouse comments.

MOTION: Timothy Boehmer moved, seconded by Alan Bloom, to approve the changes as amended and to allow legal counsel to adopt the Clearinghouse comments under numbers 1 and 4 of the Clearinghouse report, pending a final review by Doug Englebert and Yvonne Bellay. Motion carried unanimously.

APPROVAL OF MINUTES OF DECEMBER 15, 2011

MOTION: Timothy Boehmer moved, seconded by Alan Bloom, to approve the minutes of December 15, 2011 as written. Motion carried unanimously.

SECRETARY MATTERS

There was no report at this time.

EXECUTIVE DIRECTOR MATTERS

Dan Williams asked the Board's preference regarding the review of SUA applications in the future. The April Board meeting will be canceled. The Board Member Guidebook will be provided to each Board member. Board members should complete and return the signature page.

PRESENTATION OF PROPOSED STIPULATIONS

There were no stipulations.

REVIEW OF SUA APPLICATION

JAY O'NEIL K9 O'NEIL LLC

MOTION: Timothy Boehmer moved, seconded by Alan Bloom, to approve the SUA application of Jay O'Neil pending receipt of the letter from the Dane County Sheriff stating he assumes responsibility for the drugs as outlined in the SUA application. This letter must be received at the Department of Safety and Professional Services no later than April 1, 2012, and will be reviewed by the Board's Credentialing Liaison, Yvonne Bellay, to determine if the letter is acceptable. Motion carried unanimously.

BOARD DISCUSSION ITEMS

Division of Enforcement Matters

None.

Education and Examination Issues/Matters

None.

Credentialing Matters

None.

Practice Questions/Issues

None.

Legislative/Administrative Rules Matters

None.

Liaison Reports

None.

Speaking Engagement, Travel and Public Relations Requests

None.

INFORMATIONAL ITEMS

None.

NEW BUSINESS

There was no new business.

PUBLIC COMMENTS

None.

CONVENE TO CLOSED SESSION

The Board did not convene to closed session as there was no business to conduct.

ADJOURNMENT

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

The meeting adjourned at 3:50 p.m.

**CONTROLLED SUBSTANCES BOARD
TELECONFERENCE EMERGENCY MEETING MINUTES
SEPTEMBER 21, 2012**

PRESENT: Yvonne Bellay, DVM; Alan Bloom; Doug Englebert, R. Ph.; Martin Koch

EXCUSED: Timothy Boehmer, R.Ph.

STAFF: Dan Williams, Executive Director; Sharon Henes, Paralegal, Kimberly Wood, Program Assistant Supervisor

CALL TO ORDER

Doug Englebert, Chair, called the meeting to order at 8:31 a.m. A quorum of four (4) members was confirmed.

ADOPTION OF AGENDA

MOTION: Alan Bloom moved, seconded by Marty Koch, to adopt the agenda as published. Motion carried unanimously.

**ADOPTION OF CLEARINGHOUSE RULES 12-010 CREATING CSB 3 RELATING TO
THE REQUIREMENTS AND PROCEDURES FOR GRANTING
SPECIAL USE AUTHORIZATIONS**

MOTION: Yvonne Bellay moved, seconded by Alan Bloom, to adopt Clearinghouse Rule 12-010, creating CSB 3 relating to the requirements and procedures for granting special use authorizations. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 8:36 a.m.

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Kimberly Wood, Program Assistant Supervisor		2) Date When Request Submitted: 10/15/2012 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: Controlled Substances Board			
4) Meeting Date: 12/13/2012	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? 2013 Meeting Dates	
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 <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: <p>The Board should review and note its meeting dates scheduled for 2013. Please advise your Executive Director of any existing conflicts.</p>			
11) Authorization			
<i>Kimberly Wood</i>		10/15/2012	
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 Executive Assistant prior to the start of a meeting.			



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Governor Scott Walker Secretary Dave Ross

MEMO

TO: Controlled Substances Board

FROM: Kimberly Wood, Program Assistant Supervisor

DATE: November 26, 2012

RE: 2013 Meeting Dates

Board meeting dates have been scheduled as follows.

April 25	Meeting	9:00	Room 121C
August 29	Meeting	9:00	Room 121C
December 10	Meeting	9:00	Room 121A



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Overview of the Prescription Drug Monitoring Program

August 2012

- A prescription drug monitoring program (PDMP) is a statewide program that collects and stores information regarding the prescribing and dispensing of monitored prescription drugs to assist in reducing the illicit use and diversion of monitored prescription drugs
- A PDMP is an important tool that helps reduce the healthcare, social and enforcement costs that stem from prescription drug addiction and play a key role in the fight to curb the prescription drug abuse epidemic¹:
 - o PDMPs enable healthcare practitioners and pharmacists to access the information about patients prior to prescribing and/or dispensing a monitored prescription drug
 - o PDMPs enable law enforcement authorities to request the information to aid in investigating crimes associated with prescription drug diversion
- As of April, 2012, 43 states have operational PDMPs

Development of the PDMP in Wisconsin

- 2009 Wis. Act 362 directs the Department of Safety and Professional Services (Department) to seek federal grant funding and the Pharmacy Examining Board (Board) to create a PDMP through rule
- The U.S. Department of Justice awarded a grant to fund the development and deployment of PDMP to the Department in October 2011
- The PDMP is currently under development and is anticipated to be deployed in January 2013
- Development of the PDMP involves two processes:
 - o Vendor Procurement:
 - The Department worked with staff at the Department of Administration, Bureau of Procurement to develop a request for proposal (RFP)
 - The RFP was posted in May and proposals from vendors were due in June 2012
 - For more information about the procurement process, please contact Pat Conley, Procurement Manager, at pat.conley@wisconsin.gov
 - o Administrative Rule Promulgation:
 - The Board drafted rules, CR 12-009, to create Ch. Phar 18 of the Administrative Code to create and regulate the PDMP
 - The Board submitted the rule to the Legislature in March
 - The Legislature ended its review in July
 - The rule will go before the Board at its next meeting for final approval
 - For more information about the proposed rule, please see the Legislative Clearinghouse website, at <http://docs.legis.wisconsin.gov/code/chr/2012>

¹ See Controlled Substances Workgroup of the Wisconsin State Council on Alcohol and other Drug Abuse, "Reducing Wisconsin's Prescription Drug Abuse: A Call to Action," Jan. 2012 and Christine Durkin, et al., "Cost-Benefit Analysis of a Prescription Drug Monitoring Program in Wisconsin," La Follette School of Public Affairs, Dec. 20, 2010.

WHAT IF I DON'T DISPENSE ANY MONITORED PRESCRIPTION DRUGS TO PATIENTS IN WISCONSIN?

YOU HAVE TWO OPTIONS:

- 1 Submit a "zero report" for each reporting period during which you do not dispense monitored prescription drugs; or
- 2 Submit an application for an exemption from the reporting requirements. The application for an exemption is available on the website. An exemption is valid until your license expires, up to two years, or until you dispense a monitored prescription drug to a patient in Wisconsin.

HOW OFTEN MUST I SUBMIT INFORMATION?

If you are authorized to dispense monitored prescription drugs to humans, you have a 7-day reporting period. Therefore, you must submit within 7 days of dispensing a monitored prescription drug.

If you are authorized to dispense monitored prescription drugs solely to non-human animals, you have a 90-day reporting period. Therefore, you must submit within 90 days of dispensing a monitored prescription drug.

WHAT IF I DON'T DISPENSE A MONITORED PRESCRIPTION DRUG DURING A REPORTING PERIOD?

You must submit a "zero report" that indicates you did not dispense a monitored prescription drug during that reporting period.



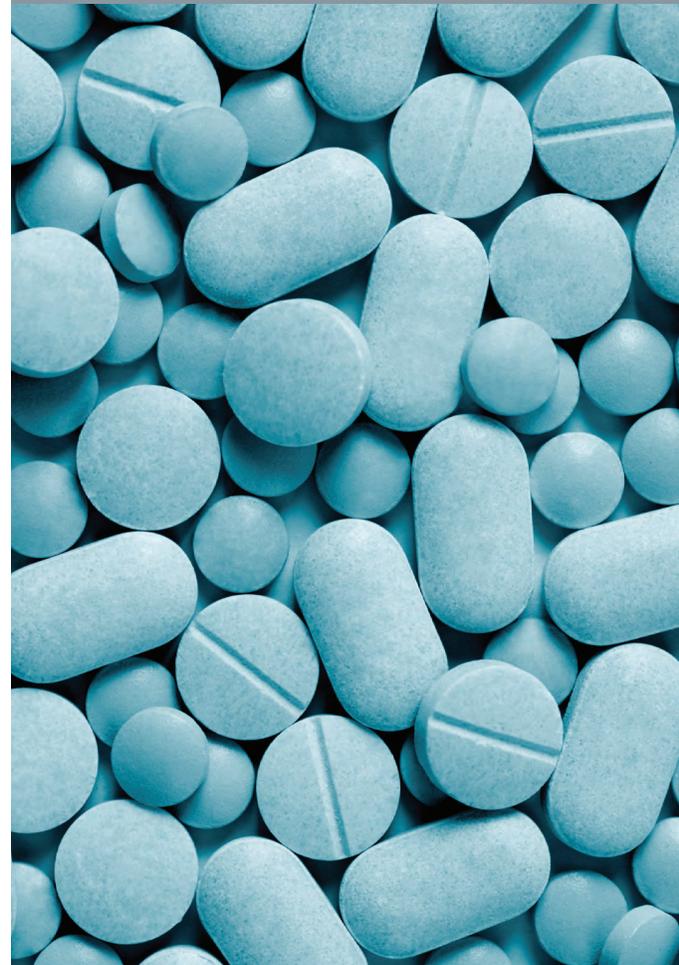
DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES

1400 E. Washington Ave.

Madison, WI 53703



AN INTRODUCTION FOR DISPENSERS



WHAT IS THE PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)?

The PDMP is a statewide program that collects information about controlled substances and other drugs that have a substantial potential for abuse that are dispensed to patients in Wisconsin. The PDMP discloses the information to users who are legally authorized to obtain the information.

WHAT ARE MONITORED PRESCRIPTION DRUGS?

Monitored prescription drugs are substances identified as a controlled substance in Schedule II, III, IV, or V by state or federal law that require a prescription order to be dispensed and Tramadol.

WHO IS REQUIRED TO SUBMIT INFORMATION TO THE PDMP?

Dispensers are required to submit information. "Dispensers" includes all pharmacies and health care practitioners licensed to dispense monitored prescription drugs to patients in Wisconsin.

WHAT DOES "DISPENSE" MEAN?

For the purposes of the PDMP, "dispense" means to give a prescribed monitored prescription drug to a patient by or pursuant to the prescription order of a practitioner, including the compounding, packaging or labeling necessary to prepare the prescribed drug. For example, a practitioner dispenses a drug when he or she gives a patient samples or other medication to consume outside of the office or medical facility. A practitioner does not dispense a drug and, therefore, does not need to submit information to the PDMP when: 1 he or she administers the drug to a patient within the office or medical facility; or, 2 he or she merely writes a prescription order to be filled elsewhere.

WHAT IF I CAN'T SUBMIT THE INFORMATION WITHIN A REPORTING PERIOD?

Prior to the required submission of the information, you must apply for an emergency waiver of the reporting period and explain the circumstances that prevent you from submitting the information in accordance with the law. Unless the Pharmacy Examining Board specifies differently, the waiver will allow an additional 7 days to submit the information without potential enforcement action being taken.

WHEN DO I NEED TO BEGIN COLLECTING INFORMATION?

The law requiring you to collect and submit information becomes effective on January 1, 2013. On that date, you must begin to collect the required information, but you will not yet be able to submit the data to the PDMP.

WHEN DO I NEED TO BEGIN SUBMITTING INFORMATION?

The law requiring you to collect and submit information becomes effective on January 1, 2013. However, on that date, you will not yet be able to submit data to the PDMP. Note that you will be required to submit the information that you collected since January 1, 2013, once the PDMP begins collecting data. The date on which PDMP will begin to collect data and more details about the reporting procedures will be available on the website and directly communicated to dispensers who will be required to submit information. For the most up-to-date information about timelines and data submission, visit the website.

WHAT INFORMATION AM I REQUIRED TO COLLECT AND SUBMIT?

You are required to collect and submit specific information about yourself, the patient, the prescriber, and the drug. Visit the website for more details about the information required to be collected and submitted.

HOW CAN I SUBMIT INFORMATION?

You must create an online account with the PDMP through which you can submit information. Once you have an account, you will have options on how to electronically submit information. All information must be submitted in accordance with the data standards established by Version 4.2 of the American Society for Automation in Pharmacy Implementation Guide for PDMPs or other format identified by the Pharmacy Examining Board. If you are unable to electronically submit information, you may apply for a waiver and submit information on paper. The application for a waiver of the electronic reporting requirements is available on the website.



IS THE INFORMATION SECURE AND CONFIDENTIAL?

Yes. The information collected by the PDMP is protected as protected health information under the HIPAA "Privacy Rule" and as confidential health care records under state law. Therefore, only authorized individuals will be able to obtain information from the PDMP. Further, the information is explicitly not subject to state open records laws.

WHAT HAPPENS TO THE INFORMATION AFTER I SUBMIT IT?

After data is submitted, it is cleansed and added to the PDMP database. Dispensers, health care practitioners and their delegates can create accounts and access the information as authorized under the law. Other categories of people who have created accounts with the PDMP and can demonstrate sufficient proof that they are legally entitled to the information may submit requests for information. Under the law, the following categories of people may obtain information under specific circumstances: patients and their authorized representatives; designated employees of government agencies; coroners and medical examiners; health care facility staff committees or accreditation or health care service review organizations; researchers; and designated staff of law enforcement agencies (pursuant to a court order in most cases).

WHERE CAN I GET MORE INFORMATION ABOUT THE PDMP?



WISCONSIN PRESCRIPTION DRUG MONITORING PROGRAM

PO Box 8935
Madison, WI 53708

E-MAIL: PDMP@wisconsin.gov
WEBSITE: <http://dsps.wi.gov/PDMP>



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This project was supported by Award No. 2011-PM-BX-0006 awarded by the Bureau of Justice Assistance, Office of Justice Programs.

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Dan Williams		2) Date When Request Submitted: 11/23/12 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: WI Controlled Substances Board			
4) Meeting Date: 12/11/12	5) Attachments: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	6) How should the item be titled on the agenda page? Discussion and consideration of Alan Bloom inquiry	
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 checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: <p>-----Original Message----- From: Bloom, Alan [mailto:abloom@mcw.edu] Sent: Friday, November 16, 2012 11:46 AM To: Englebert, Douglas A - DHS Subject: Possible agenda item for next meeting.</p> <p>Hi Doug,</p> <p>I am writing to you as CSB Chair and someone who has been on the Board longer than I, with a sense of history. The Medical College of Wisconsin's head veterinarian and director of our Animal Facility asked me how to get the CSBs opinion on the issue of the use of scheduled substances in the medical treatment of research animals. The issue is that he wishes to separate the use of drugs to prepare animals surgically for participation in research studies from the use of drugs in the studies themselves either as research tools to understand biological function or to study the actions of the drugs themselves.</p> <p>In other words, he feels that in the former case, the use of the drugs is within the scope of his practice as the Medical College veterinarian and all of the animals which are owned by the school are his patients. In the latter case the use of drugs in research should be subject to coverage by an SUA. He wishes to be able to provide anesthesia and analgesia to animals using college staff while they are being prepared for research under his practitioners license, with any subsequent use of scheduled substances in the research itself requiring DEA registration and an SUA for the individual investigator.</p> <p>Based on my experience reviewing hundreds of research SUA applications and renewals using animals, this would cover about 90% of the applications that are using controlled substances to surgically prepare animals for research. Only about 10% of the applications are actually studying drugs. This is true for both MCW and UW-Madison</p>			

11)

Authorization

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 Board Services Bureau Director.
3. If necessary, Provide original documents needing Board Chairperson signature to the Executive Assistant prior to the start of a meeting.

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Dan Williams (per Yvonne Bellay)		2) Date When Request Submitted: 11/23/12 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 	
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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 checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: <p>From: Jerry Matysik [mailto:Jerry.Matysik@eauclairewi.gov] Sent: Monday, November 05, 2012 2:18 PM To: Lo, Kaoyee - DSPS Subject: Immobilizing / Tranquilizing Dogs or other Animals</p> <p>Good afternoon, I am just looking for clarification from either you or the Controlled Substances Board. Please feel free to pass along my question to the appropriate person.</p> <p>The last few years our Animal Control Officer has obtained the required training to both euthanize animals and to immobilize (tranquelize) and then safely transport animals to a vet. We have, in the past, applied to the Board to receive permission to obtain the drugs necessary to euthanize animals. It is time for our department to again apply for the controlled substances.</p> <p>I have been told that our Police Department is able to obtain authorization from the Board to obtain the drugs needed to euthanize animals, but that those drugs <u>cannot</u> be used for tranquilizing and transporting a dangerous or vicious animal to a vet for treatment. We have discovered over the past few years that we have little need to euthanize animals in the field, but more often we need to capture an injured animal (for example – a dog hit by a car) and then safely transport that animal to a vet for treatment. As you know, injured animals are often vicious and cannot be approached safely. The use of a tranquilizer gun has proven to be the most humane alternative.</p> <p>Could you kindly clarify the alternatives available to us in this regard? In other words, if my understanding is accurate and we cannot use these controlled substances to immobilize animals for safe transport, are there other alternatives you could suggest? If not, we fear that more animals will have to be put down at the scene if officers cannot safely capture them and transport them for treatment. We did check with other area law enforcement agencies, our human shelter, and the DNR and were told that no one else in our area is able to obtain drugs for this purpose either and we therefore cannot rely on others coming to assist us should the need arise.</p> <p>Sincerely,</p> <p>Jerry Matysik Chief of Police City of Eau Claire 715-839-4975</p>			

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1) Name and Title of Person Submitting the Request: Dan Williams		2) Date When Request Submitted: 11/23/12 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: WI Controlled Substances Board			
4) Meeting Date: 12/11/12	5) Attachments: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	6) How should the item be titled on the agenda page? Discussion and consideration of: a specific motion related to delegating authority to the SUA liaisons/reviewers and the extent of that authority; a discussion, board-approval, or motion related to euthanasia injection courses.	
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 checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: See attached email chain document			
11) Authorization			
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 Board Services Bureau Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Executive Assistant prior to the start of a meeting.			

Greetings,

Someone else at the Department was able to do the research (of minutes over the last 4 years) and found Chair appointments for the SUA reviewers, but was unable to find (1) a specific motion related to delegating authority to the SUA liaisons/reviewers and the extent of that authority; or (2) a discussion, board-approval, or motion related to euthanasia injection courses.

Therefore, for the immediate issue below, I propose that we follow the course of action in the paragraph highlighted in yellow below. I also recommend that these 2 issues be placed on the agenda for the next CSB meeting.

Yvonne and Dan, please share your thoughts on this when you get a chance. For now, I think we can hold off on adding any further courses to the website.

Thanks,

Lydia Thompson
Legal Counsel, Division of Board Services

From: Bellay, Yvonne M - DATCP
Sent: Tuesday, September 04, 2012 7:49 AM
To: Thompson, Lydia - DSPS; Hendrickson, Kris - DSPS; Williams, Dan - DSPS
Cc: Lo, Kaoyee - DSPS
Subject: RE: Question regarding renewal of SUA

The board decision to have the liaisons make the determinations for approvals was made (as my memory tells me) approximately 3 or even 4 years ago. Cecilia was on the board and Dr. Treffert was president. Doug may know something more specific to help determine the exact date. Actually, the USDA SUA has been approved for several years, and I believe it is possible that the first approval was before the board specified the approved courses.

From: Thompson, Lydia - DSPS
Sent: Friday, August 31, 2012 5:11 PM
To: Hendrickson, Kris - DSPS; Williams, Dan - DSPS
Cc: Bellay, Yvonne M - DATCP; Lo, Kaoyee - DSPS
Subject: RE: Question regarding renewal of SUA

This is a good question. It is my understanding that Yvonne already has CSB approval to review and make decisions on SUA applications as one of the CSB's liaisons. I also understand that in the majority of cases, across the boards/professions served by the Department, a liaison's decision must be based on what the board currently approves or disapproves (such as activities and courses). Unfortunately, the CSB does not currently have the program referenced by the inquirer below (Chemical Immobilization and Euthanasia Recertification) on its approved list of euthanasia injection courses.

I'm thinking that if the SUA for the USDA has been previously approved by the CSB (or Yvonne or another liaison) with the Chemical Immobilization and Euthanasia Recertification course referenced below and the CSB approved it every year for several years, then it is probably a CSB approved course, based on that precedence. The SUA holder reasonably relied on the CSB's continued approval of its SUAs including the Chemical Immobilization and Euthanasia Recertification course. However, the Chemical Immobilization and Euthanasia Recertification course should be discussed with the full CSB and placed on the approved list of euthanasia injection courses, if determined to be acceptable by the Board.

Having said the above, it really all depends on the authority the CSB previously granted the SUA application liaisons and what the specific language of the motion stated. If the authority extends to allow the liaison to make the determination as to whether it is an approved course, then there is no issue and the course is "CSB approved" in this case. But if the authority allows the liaison to make a determination on the SUA application based *only* on previously "CSB approved" courses, then the liaison cannot approve the course and has been acting outside of CSB authority when SUAs were granted with non-approved courses.

Lydia Thompson

Legal Counsel, Division of Board Services

From: Bellay, Yvonne M - DATCP
Sent: Monday, August 27, 2012 8:29 AM
To: Lo, Kaoyee - DSPS
Subject: RE: Question regarding renewal of SUA

I am surprise that this issue has not come up before. I agree that the type of work that USDA is doing is specialized and would not even be covered in the board approved courses. I think that the USDA required training should be accepted for USDA employees doing the work under this SUA. However, I don't know if my opinion is sufficient or if the board will have to formally approve the course. Guess that is a question for Dan or Lydia.

From: Suckow, Jason R - APHIS [<mailto:Jason.Suckow@aphis.usda.gov>]
Sent: Friday, August 24, 2012 12:10 PM
To: Kris.Hnedrickson@wisconsin.gov; Lo, Kaoyee - DSPS
Subject: Question regarding renewal of SUA

Hi Kris,

As I was going through the checklist to renew our SUA for this coming year, I noticed that there were a number of additions. (Which I think is a good thing.) All of the new requirements are things that our agency has been doing for years. I do however have a question about the detailed nature of one particular requirement; "The authorized individual must complete a board approved Euthanasia course. For a list of approved courses go to <http://drl.wi.gov>." As part of being able to use chemical immobilizing or euthanasia drugs, USDA Wildlife Services staff are first required to take an approved training. (See attachment, USDA APHIS WS Directive 2.430) Because of the specialized nature of the work we do, it encompasses specialized training. (Please see attachment for last Chemical Immobilization and Euthanasia Recertification Agenda.) USDA APHIS WS staff do receive training certificates upon successful completion (attachment Jason Suckow Recertification Certificate) so that is not an issue, but our agency courses are not listed as approved by the Board on the web site provided.

So, my question is, if we are a federal agency utilizing DEA controlled substances under the federal laws, requirements, guidelines, and policies and our program is meeting the intent of the state requirements listed on the checklist, do we need to do anything in addition for the State of Wisconsin? If our program provides the training certificates (from our training) for each of our authorized staff will that meet the requirements of the Board (even though it is not listed on the website)?

Please advise.

Jason Suckow
Wisconsin State Director / Certified Wildlife Biologist
USDA APHIS Wildlife Services
732 Lois Drive, Sun Prairie, WI 53590
Voice: 608-837-2727 ext 18
Fax: 608-837-6754

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Dan Williams (per Yvonne Bellay)		2) Date When Request Submitted: 11/23/12 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: WI Controlled Substances Board			
4) Meeting Date: 12/11/12	5) Attachments: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	6) How should the item be titled on the agenda page? Discussion and consideration as to CSB3	
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 checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: This is a general agenda title allowing for a possible widespread discussion as to the Board and DSPS process now that CSB 3 is in effect. The discussion topic started with Dr. Bellay learning of SUA situations that had been received and what to do with possible misconduct that had been alleged.			

Chapter CSB 3

SPECIAL USE AUTHORIZATION

CSB 3.01	Authority.
CSB 3.02	Definitions.
CSB 3.03	Permits generally.
CSB 3.04	SUA permit application.

CSB 3.05	Limitations on narcotic dog trainer drugs and drug quantities.
CSB 3.06	Amendment.
CSB 3.07	Record-keeping; records retention; disclosure.
CSB 3.08	Violations.

CSB 3.01 Authority. The provisions in this chapter are adopted under the authority in s. 961.335 (8), Stats.

History: CR 12-010; cr. Register October 2012 No. 682, eff. 11-1-12.

CSB 3.02 Definitions. In this chapter:

- (1) “Board” means the controlled substances board.
- (2) “Controlled substance” has the meaning given in s. 961.01 (4), Stats.
- (3) “Humane shelter” means a facility that is intended to provide for and promote the welfare, protection, shelter, and humane treatment of animals, and that is operated by a humane society, animal welfare society, animal rescue group or other non-profit group. “Humane shelter” includes a shelter that provides foster care to animals.
- (4) “Special use” means to manufacture, obtain, possess, use, administer, or dispense a controlled substance for purposes that include, but are not limited to, scientific research, instructional activities, chemical analysis, drug-detecting animal training, and euthanasia in humane shelters.
- (5) “Special use authorization” or “SUA” means permission from the board to manufacture, obtain, possess, use, administer, or dispense a controlled substance for a special use.
- (6) “SUA permit” means a special use authorization permit granted to an individual by the board.

History: CR 12-010; cr. Register October 2012 No. 682, eff. 11-1-12.

CSB 3.03 Permits generally. (1) No individual may manufacture, obtain, possess, use, administer, or dispense a controlled substance for a special use without a valid SUA permit for such purpose.

(2) An SUA permit may be issued to an individual only. Entities are not eligible to receive an SUA permit, except that an individual may be designated and authorized to receive the permit for a college or university department, research unit, or similar administrative organization unit. Students, laboratory technicians, research specialists, or chemical analysts under the designee’s supervision may possess and use the substances named in the designee’s permit for the authorized purposes without obtaining an individual permit.

(3) An SUA permit authorizes the holder to manufacture, obtain, possess, use, administer, or dispense the controlled substances specified in the permit and in the amounts specified in the permit. A permit holder shall use the authorized controlled substances only in the manner delineated in the SUA permit application, and as approved by the board. Any deviation from the permit’s specifications and subsequent amendments shall constitute a violation of the permit, and may result in revocation or suspension of the permit as set forth in s. CSB 3.08 (2).

(4) An SUA permit is valid for one year from the date of issuance. An SUA permit shall not be extended or renewed. A new application shall be completed and a new permit shall be granted to continue authorization beyond an existing permit’s expiration date.

History: CR 12-010; cr. Register October 2012 No. 682, eff. 11-1-12.

CSB 3.04 SUA permit application. (1) Every applicant for an SUA permit shall:

(a) Submit a completed application and any required checklists using forms provided by the board. A complete application shall include a detailed description of the anticipated uses for each identified controlled substance in Schedules I to V of ch. 961, Stats., including each identified controlled substance by name and schedule and the protocols for such uses.

Note: Application forms and checklists are available upon request to the board office at 1400 E. Washington Ave., P.O. Box 8935, Madison, Wisconsin 53708, or online at <http://dps.wi.gov>, under “Professions,” then “Controlled Substance Special Use Authorization.”

(b) Pay the applicable permit fee of \$25 as set forth in s. 961.335, Stats. No fee for an SUA permit may be charged to an employee of a state agency or institution if the permit is necessary to perform employment functions.

(c) Provide proof that the applicant has submitted an application for registration with the federal drug enforcement administration.

(d) Provide proof of the applicant’s compliance with the board’s requirements for maintaining the physical security of the controlled substances identified in the application.

(e) Provide the calculations that led to the amounts requested in the application.

(f) Any individual applying for an SUA permit shall provide any other information or documentation requested by the board.

(2) In addition to sub. (1), researchers shall also provide the following:

(a) A detailed one-page description of each research protocol that involves the use of controlled substances.

(b) For research involving animals, verification of Institutional Animal Care and Use Committee approval.

(c) For research involving human subjects, verification of Institutional Review Board approval.

(3) In addition to sub. (1), humane shelters shall also provide all of the following:

(a) Estimates as to the number of animals and dosage per animal.

(b) Documentation of completion of a board-approved euthanasia by injection course by each staff member performing euthanasia.

(4) In addition to sub. (1), narcotic dog trainers shall also provide the following:

(a) Unless other documentation is required by the board, a letter from the sheriff or chief of police, in the jurisdiction where the controlled substances are stored, that includes all of the following for dog training purposes:

1. Authorizing possession of controlled substances.
2. Accepting responsibility for the narcotic dog trainer.
3. Agreeing to supervise the narcotic dog trainer’s storage and use of controlled substances.

(b) Verification of membership in a board-approved national or Wisconsin police dog association for each narcotic dog trainer.

(c) For private narcotic dog trainers, an appearance before the board shall be required.

(5) In addition to sub. (1), municipal law enforcement animal control shall also provide all of the following:

(a) Unless other documentation is required by the board, a letter from the sheriff or chief of police, in the jurisdiction where the controlled substances are stored, that includes all of the following for euthanasia purposes:

1. Authorizing possession of controlled substances.
2. Accepting responsibility for the animal control officer.
3. Agreeing to supervise the animal control officer's storage and use of controlled substances.

(b) Documentation of completion of a board-approved euthanasia course by the officer performing euthanasia.

(6) In addition to sub. (1), analytical labs shall also provide all of the following:

(a) An inventory listing the total weight in grams of each controlled substance in the lab or intended for purchase for the lab.

(b) Whenever the lab purchases or otherwise adds to its inventory a new controlled substance or an additional amount of a controlled substance that was not previously authorized in a permit, an amended SUA application that includes the total weight in grams for each such new or additional substance.

(c) A detailed description of standard operating procedures relating to the use of controlled substances that includes the receipt, use, and disposition of controlled substances.

(7) The board may request an appearance before the board if additional information is required.

History: CR 12-010: cr. Register October 2012 No. 682, eff. 11-1-12.

CSB 3.05 Limitations on narcotic dog trainer drugs and drug quantities. **(1)** Narcotic dog trainers shall be limited to having possession of the following drugs and quantities at any given time during the permit period:

(a) Up to 2 kilograms of marijuana. Marijuana may require periodic replacement during the permit period. Total use per year, taking into account replacement, shall be requested.

(b) Up to 30 grams of cocaine.

(c) Up to 30 grams of cocaine base, commonly known as crack cocaine.

(d) Up to 30 grams of heroin.

(e) Up to 30 grams of methamphetamine.

(2) A trainer may request, and the board may approve, with appropriate justification by the trainer, other controlled substances or different quantities of controlled substances.

History: CR 12-010: cr. Register October 2012 No. 682, eff. 11-1-12.

CSB 3.06 Amendment. **(1)** A permit shall be effective only for the individual, substances, and project specified on its face and for additional projects which derive directly from the stated project. An individual holding a valid SUA permit may apply for an amendment to the permit by filing a written request with the board indicating the justification for the amendment and by paying a \$5 fee. The board may approve a request to amend a permit for any of the following reasons:

(a) A change to the original permit holder.

(b) The addition of new individuals to the permit who are participating in the functions for which the authorization was approved.

(c) An increase in the amount of a previously authorized controlled substance.

(d) The addition of specific controlled substances or schedules not previously authorized.

(e) The addition of further activity in accordance with s. 961.335 (5), Stats.

(2) An application for an amendment shall be submitted to the department and approved by the board prior to a permit holder operating under the terms of the amendment.

(3) Individuals applying for an amendment shall provide any other information or documentation requested by the board including information and documentation related to previous special use authorization permits.

History: CR 12-010: cr. Register October 2012 No. 682, eff. 11-1-12.

CSB 3.07 Record-keeping; records retention; disclosure. **(1)** A permit holder shall maintain updated and accurate records of all of the following:

(a) The purchase of controlled substances pursuant to the permit, including receipts.

(b) The disbursement, use, and disposition of all controlled substances authorized by the permit.

(c) The total weight in grams of each controlled substance on hand.

(d) Documentation related to any discrepancies in a controlled substance inventory and usage, and all documentation related to investigation of such discrepancies.

(2) A permit holder shall retain the records described in sub. (1) for 4 years after the expiration of the special use authorization permit.

(3) A permit holder shall provide copies of the original records upon request of the board or the department of safety and professional services, except for those that are protected from disclosure by s. 961.335 (7), Stats.

History: CR 12-010: cr. Register October 2012 No. 682, eff. 11-1-12.

CSB 3.08 Violations. **(1)** The following acts shall constitute a violation of an SUA permit:

(a) Any deviation from the permit's specifications related to controlled substances, schedules of drugs, or amounts authorized.

(b) Failure to comply with this chapter or s. 961.335, Stats.

(c) Failure to maintain physical security requirements for controlled substances as required by state and federal law.

(d) Failure to comply with board-approved euthanasia standards.

Note: The board considers the most current version of the euthanasia standards as stated in the American Veterinary Medical Association (AVMA) panel on euthanasia available at <http://www.avma.org>.

(e) Failure to notify the board of the revocation or limitation of a drug enforcement administration registration, within 3 business days of the revocation or limitation.

(2) Any violation of a special use authorization permit may, in the board's discretion, result in the suspension or revocation of the special use authorization permit.

History: CR 12-010: cr. Register October 2012 No. 682, eff. 11-1-12.

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Dan Williams		2) Date When Request Submitted: 11/23/12 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: WI Controlled Substances Board			
4) Meeting Date: 12/11/12	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Discussion and Consideration of Scope Statement as to the Emergency Scheduling of controlled substances.	
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 style="margin-left: 40px;">A) See 2 attached letters from the Office of the Brown County District Attorney.</p> <p style="margin-left: 40px;">B) See attached email dated 11/14/12 from Martin Koch.</p>			
11) Authorization <hr/> Signature of person making this request Date <hr/> Supervisor (if required) Date <hr/> 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 Board Services Bureau Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Executive Assistant prior to the start of a meeting.			

OFFICE OF THE DISTRICT ATTORNEY

Brown County

300 E. WALNUT STREET, P.O. BOX 23600
GREEN BAY, WI 54305-3600
PHONE (920) 448-4190, FAX (920) 448-4189

DAVID L. LASEE
DISTRICT ATTORNEY

DEPUTY DISTRICT ATTORNEYS
Lawrence J. Lasee
Dana J. Johnson

VICTIM WITNESS COORDINATOR
Karen H. Dorau
(920) 448-4194

ASSISTANT DISTRICT ATTORNEYS

Mary M. Kerrigan-Mares
Wendy W. Lemkuil
Amy R.G. Pautzke
John F. Luetscher
Kevin C. Greene
Eric R. Enli
Thomas J. Coaty
Beau G. Liegeois
Kate R. Zuidmulder
Sarah E. Belair
Cynthia L. Vopal

September 27, 2012

Wisconsin Department of Safety and Professional Services
Controlled Substances Board
P.O. Box 8935
1400 E. Washington Avenue
Madison, WI 53708-8935

Re: Brown County Case Nos. 12CF1091 & 12CF1092

To Whom It May Concern:

The Brown County District Attorney's Office is currently prosecuting two cases relating to the possession or delivery of substances believed to be analogs of controlled substances listed in Chapter 961 of the Wisconsin Statutes. A substance was sent to the Wisconsin State Crime Laboratory in Wausau for analysis and was given Lab Case Number W12-1710. With respect to lab case W12-1710, Analyst Billie J. Robbins analyzed the substance and identified the presence of a chemical substance known as (1-pentyl-1H-indol-3-yl) (2, 2, 3,3-tetramethylcyclopropyl)methanone (UR-144) and (1-5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (XLR-11), which are not controlled substances. (See Attached Exhibit 1). In following up with Terrence Boos, a chemist with the Drug Enforcement Administration (DEA), he indicated that UR-144 and XLR-11 have a chemical structure substantially similar to that of JWH-018, which is a restricted controlled substance and also the similarities of the effects on the user. In support of this position, Boos further pointed to DEA reports for UR-144 dated April, 2012 and XLR-11, dated May, 2012, which show the molecular similarity between UR-144 and XLR-11 with JWH-018 and further emphasize their similarities. (See Attached Exhibit 2).

It is my understanding that the district attorney is required to provide information to this board relevant to emergency scheduling of each of the above-referenced substances. It is intended that this communication satisfy this office's requirements under Section 961.25, Wisconsin Statutes, and serve

as a request that the Wisconsin Controlled Substance Board review UR-144 and XLR-11 for emergency scheduling as contemplated under Section 961.11(4m). Please notify me of the specific procedure that needs to be followed to have this request considered or of any additional information you may require in making your determination.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in cursive script, appearing to read "Wendy W. Lemkuil".

Wendy W. Lemkuil
Assistant District Attorney

WWL/lal

Enclosure



Exhibit 1 No. 4340 P. 2

Wisconsin Department of Justice
Division of Law Enforcement Services
State Crime Laboratory - Wausau
7100 Stewart Avenue
Wausau, WI 54401-8410
(715) 845-8826
FAX (715) 848-5833

Submitting Agency:

David Poteat
Brown County Drug Task Force
P.O. Box 22082
Green Bay WI 54305-2082

Date: August 16, 2012

Lab Case: W12-1710

Agency No.: 12-0255002

Laboratory Analyst:

Billie J. Robbins

*KAT
8/16/12*

Billie J. Robbins
Controlled Substances Unit

Case Name: Technical Assistance (S)

I do hereby certify this document, consisting of 1 page(s), to be a true and correct report of the findings of the State Crime Laboratory on the items examined as shown by this report. This report contains the conclusions of the above signed analyst.

J.B. Van Hollen
ATTORNEY GENERAL

[Signature]
DESIGNEE

<u>Item</u>	<u>Description / Source</u>
A	A heat-sealed plastic bag containing 4.671 grams of plant material.

Examinations of the plant material from item A identified the presence of (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), which is not a controlled substance. The presence of (1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (XLR-11) was also indicated in the plant material from item A.



CASE ACTIVITY REPORT
BROWN COUNTY DRUG TASK FORCE

N/I Windorff

CASE #	DATE	ACTIVITY
12-0255-003	09-06-12	Supplement

ACTIVITY: On 09-06-12, I made phone contact with Terrence Boos who is a chemist with the Drug Enforcement Administration Office (DEA). The purpose of the conversation was to speak with Boos on the analog status of chemicals (1-pentyl-1H-indol-3-yl) (2,2,3,3-tetramethylcyclopropyl)methanone (UR-144) and (1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (XLR-11).

I was talking with Boos and he advised me that it is the DEA's position that both UR-144 and XLR-11 meet both the chemical and the pharmacological definitions of a controlled substance analog as required in the Controlled Substances Act.

Boos pointed to reports for UR144 dated April 2012 and XLR11 dated May 2012 showing the macular similarity between UR144 and XLR-11 with JWH-018 which is a restricted controlled substance and also the similarities of the effects that it has on the user.

See attached DEA reports for further details.

N/I R Windorff #727

Exhibit 2

Drug Enforcement Administration
Office of Diversion Control
Drug & Chemical Evaluation Section
8701 Morrisette Drive
Springfield, Virginia 22152
(202) 307-7183

1-Pentyl-3-(2,2,3,3-
tetramethylcyclopropoyl)indole
(UR-144) Analogue Status



April 2012

Analogue Statute of the Controlled Substances Act

The Controlled Substances Act (CSA) was amended in 1986 by enactment of the Controlled Substance Analogue Enforcement Act. This law provides for controlled substance analogues, to the extent that they are intended for human consumption, to be treated as Schedule I controlled substances for the purposes of criminal prosecution. The term "controlled substance analogue" means a substance which: (1) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II; (2) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or (3) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II. [Title 21 United States Code 802(32)(A)].

If evidence can be accumulated that the substance in question is intended for human consumption and is not already controlled under the CSA or legally marketed in the United States, the use of the analogue provision of the CSA should be considered (Title 21 United States Code 813).

(1) *1-Pentyl-3-(2,2,3,3-tetramethylcyclopropoyl)indole (UR-144) shares substantial chemical structural similarities with the Schedule I substance, 1-pentyl-3-(1-naphthoyl)indole (JWH-018)*

The chemical structures of UR-144 and JWH-018 are substantially similar. Both compounds share the same core indole structure as depicted in Figure 1 with substitutions at the 1 and 3 positions of this fused bi-cyclic ring system.

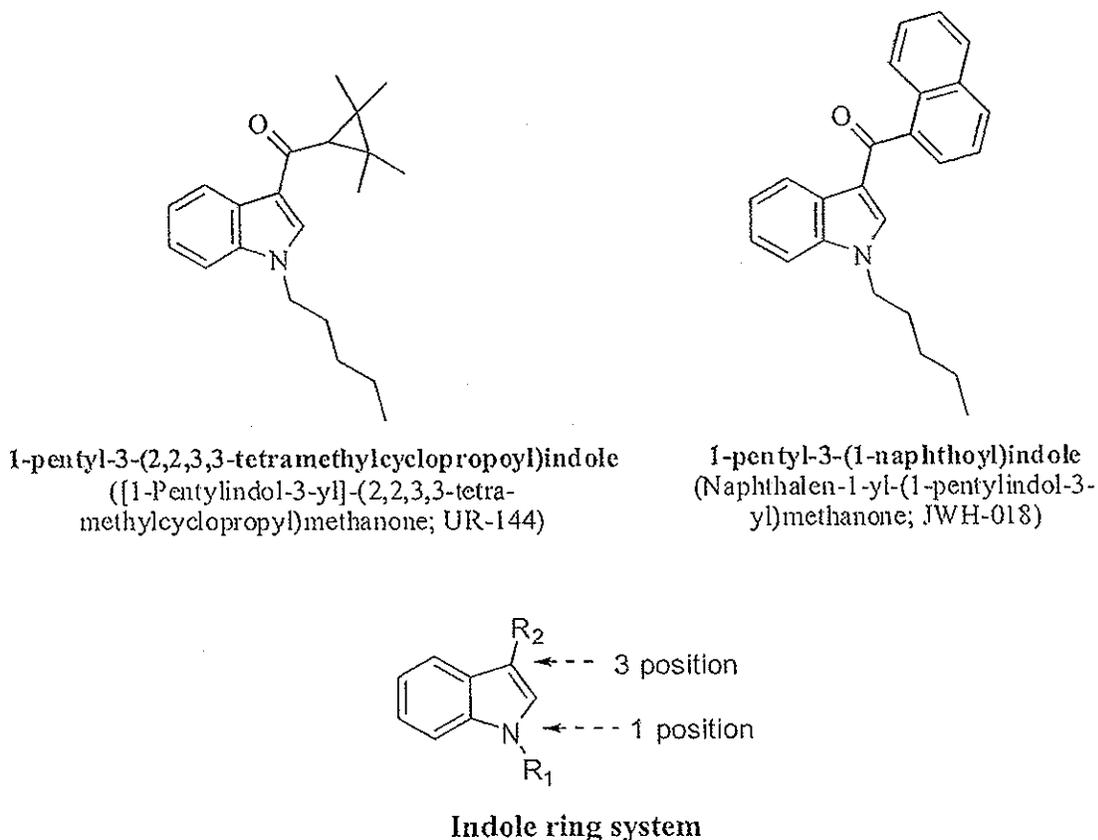


Figure 1. Structures of UR-144, JWH-018, and indole ring system

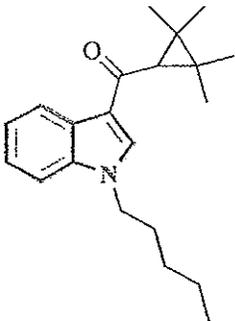
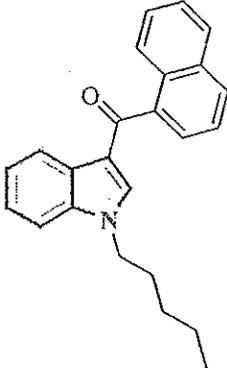
Figure 1 depicts the structures of UR-144, JWH-018, and the indole ring system. The core ring system is substituted at the indole-1 and -3 positions to give both UR-144 and JWH-018. Both substances are substituted at the 3-position with an acyl group, a carbonyl group (ketone) linked to a ring system and at the 1-position with an alkyl group. The alkyl group at the 1-position for both UR-144 and JWH-018 is a five carbon unit chain known as a pentyl group.

Studies concerning the aminoalkylindole structural class have focused primarily on varying the indole nitrogen and 3-position substituents. The core indole became a framework for continued investigations with the early work by Sterling-Winthrop that led to pravadoline and WIN-55212-2 (D'Ambra *et al.*, 1992). Several other groups expanded this investigation of structure activity relationships including the laboratories of Huffman and co-workers and Makriyannis and co-workers (Huffman, 2009). The scientific

literature and patent literature details further substitutions of the aminoalkylindole structural class with specific substitutions at the 3-position of the indole core structure to incorporate aromatic and non-aromatic ring systems. Bell (1986) reported on the preparation of cyclohexyl ketones and the work of Frost and co-workers is an extension. A series of 3-tetramethylcyclopropyl ketone substituted indoles were prepared and evaluated (Frost *et al.*, 2008). These investigations led to the further synthesis and evaluation of UR-144 and series of structurally related nonaromatic acyl substituted substances (Frost *et al.*, 2010).

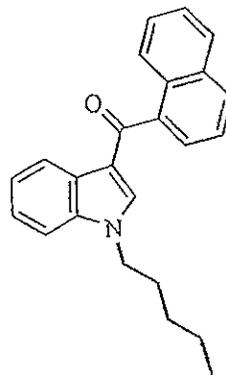
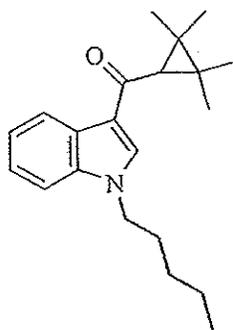
Both substances share the core indole ring system. The nitrogen of the indole, 1-position is substituted by an alkyl moiety. The alkyl group attached to the nitrogen for both UR-144 and JWH-018 is a five carbon chain known as a pentyl group. The indole 3-position incorporates a carbonyl (C=O) group which is further substituted with a cyclic ring system. Table 1 further highlights the structural similarities between UR-144 and JWH-018.

Table 1. Shared structural features

Structural feature	UR-144	JWH-018
A. Indole core structure		

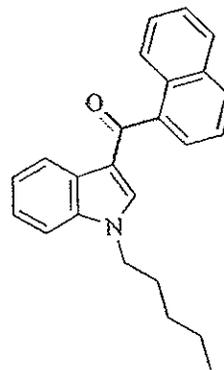
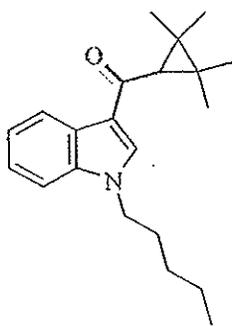
B.

Indole 1-
position
substitution



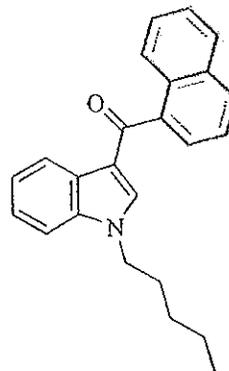
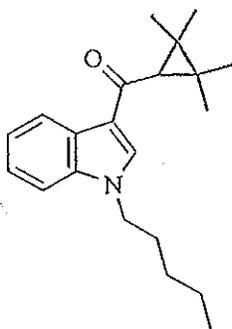
C.

Indole 3-
position
carbonyl
substitution



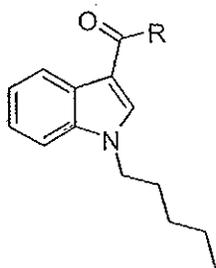
D.

Carbonyl
substitution



The shared structural features are further highlighted in Figure 2, below. The chemical structures for both UR-144 and JWH-018 are substituted at the same position with a ring system and the overlap of both substances details the high degree of conservation in chemical structure between the two substances. As previously noted, these substances are representative of the aminoalkylindole structural class.

(A)



Substance	R =	Name
JWH-018		naphthyl
UR-144		tetramethylcyclopropyl

(B)

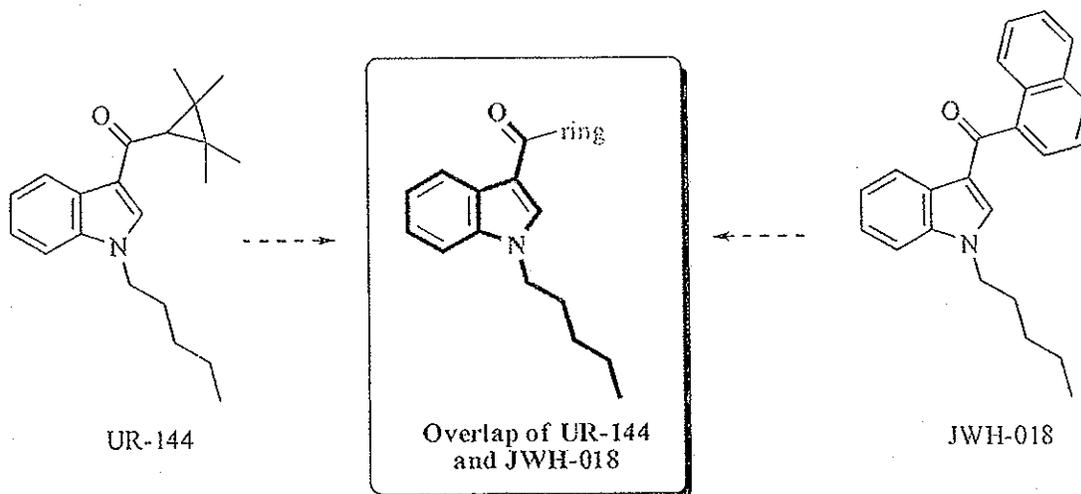


Figure 2. (A) Comparison of site specific substitution for UR-144 and JWH-018 and (B) the overlap of the two chemical structures, bold features highlight shared chemical structure.

The difference between these two substances is the ring structure attached to the 3-position the carbonyl group, alicyclic vs. aryl ring system. UR-144 incorporates a tetramethylcyclopropyl group, whereas, JWH-018 incorporates a naphthyl group. Other than this difference, the remainder of the chemical structure for both UR-144 and JWH-018 is the same. Therefore, based on the above analysis, UR-144 is substantially similar in chemical structure to JWH-018 and meets the first criterion of the definition of a controlled substance analogue*.

[*Note: According to 21 U.S.C. 802(32), the first criterion of the definition of a controlled substance analogue requires consideration of physical structure only. While various functional groups at different positions may alter certain physicochemical properties (solubility, polarity, melting point, etc.), these physicochemical properties are not considered in making a determination regarding structural similarity. However, they may be considered in making a determination regarding pharmacological similarity under the second criterion of the definition of an analogue.]

References

Bell MR (1986). 3-Carboxy-1-amino-1H-indoles as useful analgesics. EP171037.

D'Ambra TE, Estep KD, Bell MA, Eissenstat MA, Josef KA, Ward SJ, Haycock DA, Baizman ER, Casiano FM, Beglin NC, Chippari SM, Grego JD, Kullnig RK, and Daley GT (1992). **Conformationally restrained analogues of pravadoline: nanomolar potent, enantioselective, (aminoalkyl)indole agonists of the cannabinoid receptor.** *Journal of Medicinal Chemistry* 35, 124-135.

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Huffman JW (2009). **Cannabinimetic indoles, pyrroles, and indenes: Structure-activity relationships and receptor interactions.** *Cannabinoid Receptors*, Reggio PH, Ed, Chapter 3, 49-98, Humana, New York

(2) *1-Pentyl-3-(2,2,3,3-tetramethylcyclopropyl)indole (UR-144) is likely to share substantial pharmacological effects similarity with the Schedule I substance, 1-pentyl-3-(1-naphthoyl)indole (JWH-018)*

- Classical cannabinoids, such as the primary psychoactive constituent of marijuana, Δ^9 -tetrahydrocannabinol (Δ^9 -THC) produces pharmacological effects via specific receptors in the body. The complex effects of cannabinoids are considered to be mediated through at least two distinct G-protein coupled transmembrane receptors designated as CB1 and CB2. The CB1 receptors are found predominately in the central nervous system, and are attributed to most of the overt pharmacological effects

of cannabinoids. The CB1 receptors are thought to be responsible for the euphoric and psychoactive effects (Wells and Ott, 2011). The CB2 receptors are found primarily in the periphery and expressed in the immune system.

- UR-144 binds to both CB1 and CB2 receptors with reported binding affinities (K_i) of 150 and 1.8 nM, respectively (Frost *et al.*, 2010). JWH-018 binds to the CB1 and CB2 receptors with reported binding affinities (K_i) of 9.0 and 2.9 nM, respectively (Aung *et al.*, 2000; Wiley *et al.*, 1998).
- CB1 receptor agonists can be divided into four structural classes (1) classic cannabinoids; (2) non-classical cannabinoids; (3) aminoalkylindoles; and (4) endogenous cannabinoids (Reggio, 2003).
- UR-144, similar to JWH-018, is a substance representative of the aminoalkylindole structural class. Aminoalkylindoles are known to exhibit typical cannabinoid pharmacology *in vivo* (D'Ambra *et al.*, 1992; Compton *et al.*, 1992).

Based on the above mentioned receptor binding data and structure-activity relationship information, UR-144 is likely to have cannabinoid agonist properties similar to that of JWH-018.

(3) 1-Pentyl-3-(2,2,3,3-tetramethylcyclopropyl)indole (UR-144) was represented by the seller to have a pharmacological effect substantially similar to a Schedule I or II controlled substance (example: "this acts just like JWH-018"). These criteria are found at 21 U.S.C. § 802(32)(A).

The third criterion may be established from evidence collected by the investigators (example: conversations or e-mail with suspects).

Conclusion

Based on the above information, UR-144 is substantially similar in chemical structure to JWH-018 and meets the first criterion of the definition of a controlled substance analogue. Based on receptor binding affinities, it is inferred that UR-144 is likely to have substantially similar pharmacological effects on the central nervous system.

as the schedule I substance, JWH-018 and meets the second criterion of the definition of a controlled substance analogue. Depending on the individual case history, UR-144 may meet the third criterion of the definition of a controlled substance analogue. The third criterion may be established from evidence collected by the investigators (example: conversations or e-mail with suspects).

References

- Frost JM, Dart MJ, Tietje KR, Garrison TR, Grayson GK, Daza AV, El-Kouhen OF, Miller LN, Li L, Yao BB, Hsieh GC, Pai M, Zhu CZ, Chandran P, and Meyer MD. **Indol-3-yl-tetramethylcyclopropyl ketones: effects of indole ring substitution on CB2 cannabinoid receptor activity.** *Journal of Medicinal Chemistry* 51:1904-1912.
- Frost JM, Dart MJ, Tietje KR, Garrison TR, Grayson GK, Daza AV, El-Kouhen OF, Yao BB, Hsieh GC, Pai M, Zhu CZ, Chandran P, and Meyer MD (2010). **Indol-3-ylcycloalkyl ketones: effects of N1 substituted indole side chain variations on CB2 cannabinoid receptor activity.** *Journal of Medicinal Chemistry* 53:295-315.
- Aung MM, Griffin G, Huffman JW, Wu M-J, Keel C, Yang B, Showalter VM, Abood ME, and Martin BR (2000). **Influence of the N-1 alkyl chain length of cannabimimetic indoles upon CB1 and CB2 receptor binding.** *Drug and Alcohol Dependence* 60:133-140.
- Compton DR, Gold LH, Ward SJ, Balster RL, and Martin BR (1992). **Aminoalkylindole analogs: cannabimimetic activity of a class of compounds structurally distinct from Δ^9 -Tetrahydrocannabinol.** *Journal of Pharmacology and Experimental Therapeutics* 263(3): 1118-1126.
- D'Ambra TE, Estep KG, Bell MR, Eissenstat MA, Josef KA, Ward SJ, Haycock DA, Baizman ER, Casiano FM, and Beglin (1992). **Conformationally restrained analogues of pravadoline: nanomolar potent, enantioselective, (aminoalkyl)indole agonists of the cannabinoid receptor.** *Journal of Medicinal Chemistry* 35(1):124-135.
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- Wells DL and Ott CA (2011). **The "new" marijuana.** *The Annals of Pharmacotherapy* 45(3), 414-417.
- Wiley JL, Compton DR, Dai D, Lainton JAH, Phillips M, Huffman JW, and Martin BR (1998). **Structure activity relationships of indole- and pyrrole-derived cannabinoids.** *Journal of Pharmacology and Experimental Therapeutics* 285(3):995-1004.

Drug Enforcement Administration
Office of Diversion Control
Drug & Chemical Evaluation Section
8701 Morrisette Drive
Springfield, Virginia 22152
(202) 307-7183

1-(5-fluoro-pentyl)-3-(2,2,3,3-
tetramethylcyclopropoyl)indole

(5-fluoro-UR-144; XLR11)

Analogue Status



May 2012

Analogue Statute of the Controlled Substances Act

The Controlled Substances Act (CSA) was amended in 1986 by enactment of the Controlled Substance Analogue Enforcement Act. This law provides for controlled substance analogues, to the extent that they are intended for human consumption, to be treated as Schedule I controlled substances for the purposes of criminal prosecution. The term "controlled substance analogue" means a substance which: (1) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II; (2) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or (3) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II. [Title 21 United States Code 802(32)(A)].

If evidence can be accumulated that the substance in question is intended for human consumption and is not already controlled under the CSA or legally marketed in the United States, the use of the analogue provision of the CSA should be considered (Title 21 United States Code 813).

(1) *1-(5-Fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropyl)indole (5-fluoro-UR-144; XLR11) shares substantial chemical structural similarities with the Schedule I substance, 1-pentyl-3-(1-naphthoyl)indole (JWH-018)*

The chemical structures of 5-fluoro-UR-144 and JWH-018 are substantially similar. Both compounds share the same core indole structure as depicted in Figure 1 with substitutions at the 1 and 3 positions of this fused bi-cyclic ring system.

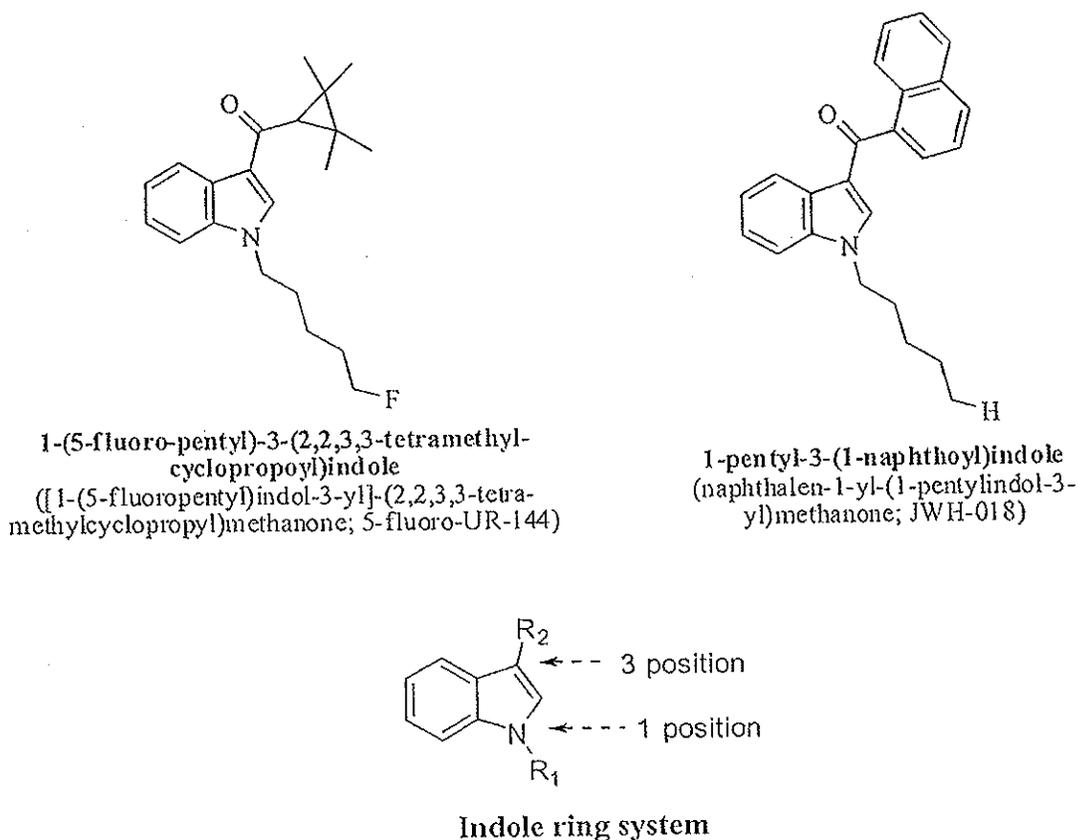


Figure 1. Structures of 5-fluoro-UR-144, JWH-018, and indole ring system

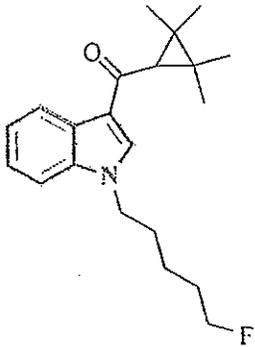
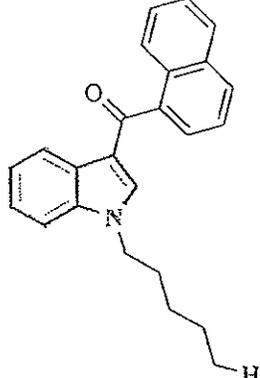
Figure 1 depicts the structures of 5-fluoro-UR-144, JWH-018, and the indole ring system. The core ring system is substituted at the indole-1 and -3 positions to give both 5-fluoro-UR-144 and JWH-018. Both substances are substituted at the 3-position with an acyl group, a carbonyl group (ketone) linked to a ring system and at the 1-position with an alkyl group, a substituted alkyl group in the case of 5-fluoro-UR-144. The alkyl group at the 1-position for both 5-fluoro-UR-144 and JWH-018 is a five carbon unit chain, known as a pentyl group and for 5-fluoro-UR-144 the terminal position of the alkyl chain is substituted with a fluoride (F) atom.

Studies concerning the aminoalkylindole structural class have focused primarily on varying the indole nitrogen and 3-position substituents. The core indole became a framework for continued investigations with the early work by Sterling-Winthrop that led to pravadoline and WIN-55212-2 (D'Ambra *et al.*, 1992). Several other groups expanded

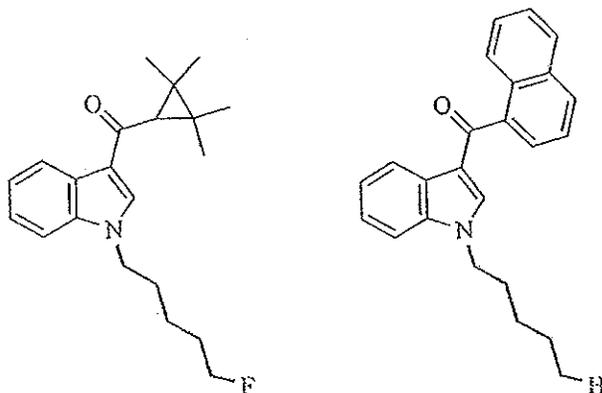
this investigation of structure activity relationships pertaining to this structural class, most notably the laboratories of Huffman and co-workers and Makriyannis and co-workers (Huffman, 2009). The scientific literature and patent literature details further substitutions of the aminoalkylindole structural class with specific substitutions at the 3-position of the indole core structure to incorporate aromatic and non-aromatic ring systems. Bell (1986) reported on the preparation of cyclohexyl ketones and the work of Frost and co-workers is an extension. A series of 3-tetramethylcyclopropyl ketone substituted indoles were prepared and evaluated (Frost *et al.*, 2008). These investigations led to the further synthesis and evaluation of nonaromatic acyl substituted substances structurally similar to 5-fluoro-UR-144 that included the substance UR-144 (Frost *et al.*, 2010).

Table 1 further highlights the structural similarities between 5-fluoro-UR-144 and JWH-018. Both substances share the core indole ring system. The nitrogen of the indole, 1-position is substituted by an alkyl moiety. Attached to the nitrogen for both 5-fluoro-UR-144 and JWH-018 is an alkyl group consisting of a five carbon chain known as a pentyl group. The terminal position of the alkyl group is substituted with a fluoride atom in 5-fluoro-UR-144, the halogen substituted alkyl group is known as a haloalkyl. The indole 3-position incorporates a carbonyl (C=O) group which is further substituted with a cyclic ring system.

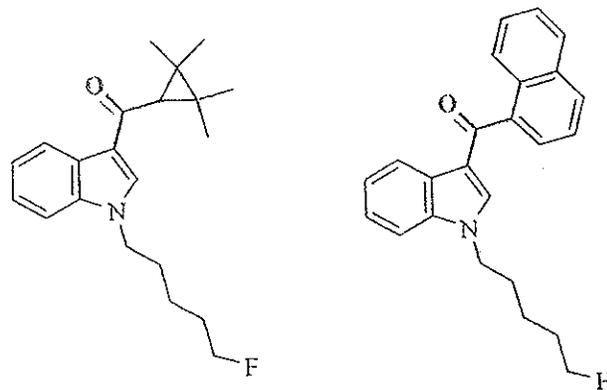
Table 1. Shared structural features

Structural feature	5-fluoro-UR-144	JWH-018
A. Indole core structure		

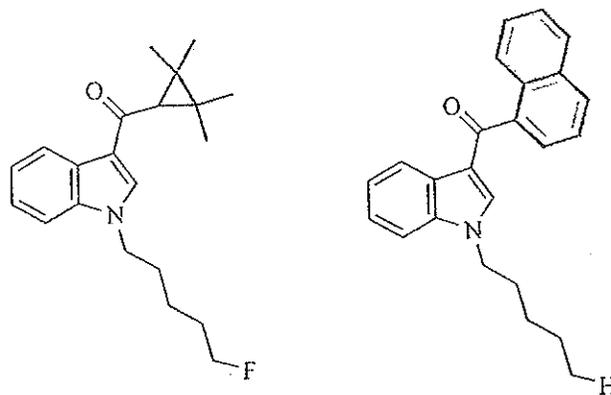
B. Indole 1-position
substitution



C. Indole 3-position
carbonyl
substitution



D. Carbonyl
substitution



The substitutions are further highlighted below with the overlap of the two chemical structures.

differences, the remainder of the chemical structure for these two substances is the same. Therefore, based on the above analysis, 5-fluoro-UR-144 is substantially similar in chemical structure to JWH-018 and meets the first criterion of the definition of a controlled substance analogue*.

[*Note: According to 21 U.S.C. 802(32), the first criterion of the definition of a controlled substance analogue requires consideration of physical structure only. While various functional groups at different positions may alter certain physicochemical properties (solubility, polarity, melting point, etc.), these physicochemical properties are not considered in making a determination regarding structural similarity. However, they may be considered in making a determination regarding pharmacological similarity under the second criterion of the definition of an analogue.]

References

Bell MR (1986). 3-Carboxy-1-amino-1H-indoles as useful analgesics. EP171037.

D'Ambra TE, Estep KD, Bell MA, Eissenstat MA, Josef KA, Ward SJ, Haycock DA, Baizman ER, Casiano FM, Beglin NC, Chippari SM, Grego JD, Kullnig RK, and Daley GT (1992). **Conformationally restrained analogues of pravadoline: nanomolar potent, enantioselective, (aminoalkyl)indole agonists of the cannabinoid receptor.** *Journal of Medicinal Chemistry* 35, 124-135.

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(2) *1-(5-Fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropyl)indole (5-fluoro-UR-144; XLR11) is likely to have pharmacological effects on the central nervous system that are substantially similar to that of the Schedule I substance, 1-pentyl-3-(1-naphthoyl)indole (JWH-018)*

- Classical cannabinoids, such as the primary psychoactive constituent of marijuana, Δ^9 -tetrahydrocannabinol (Δ^9 -THC) produces pharmacological effects via specific receptors in the body. The complex effects of cannabinoids are considered to be mediated through at least two distinct G-protein coupled transmembrane receptors designated as CB1 and CB2. The CB1 receptors are found predominately in the central nervous system, and are attributed to most of the overt pharmacological effects of cannabinoids. The CB1 receptors are thought to be responsible for the euphoric and psychoactive effects (Wells and Ott, 2011). The CB2 receptors are found primarily in the periphery and expressed in the immune system.
- UR-144, a close structural congener of 5-fluoro-UR-144 differing only by lacking the fluoride atom on the alkyl chain, binds to both CB1 and CB2 receptors with reported binding affinities (K_i) of 150 and 1.8 nM, respectively (Frost *et al.*, 2010). JWH-018 binds to the CB1 and CB2 receptors with reported binding affinities (K_i) of 9.0 and 2.9 nM, respectively (Aung *et al.*, 2000; Wiley *et al.*, 1998).
- Based on trends from similar modifications (example AM-2201 vs. JWH-018), the substitution of a fluoride atom on the terminal position of the five carbon alkyl chain (pentyl) is well tolerated. Thus it would be anticipated that the substitution of a fluoride atom on the alkyl chain of UR-144 would retain similar binding affinity for the CB1 receptor.
 - Examples of fluoride atom substitution on binding affinity
 - AM-2201 binds to both CB1 and CB2 receptors with reported binding affinities (K_i) of 1.0 and 2.6 nM, respectively (US 6,900,236 B1; EP 1,702,617 A1; US 2005/0119234 A1). JWH-018 binds to the CB1 and CB2 receptors with reported binding affinities (K_i) of 9.0 and 2.9 nM, respectively (Aung *et al.*, 2000; Wiley *et al.*, 1998).
 - AM1248 binds to both CB1 and CB2 receptors with reported binding affinities (K_i) of 1.3 and 10.5 nM, respectively (US

6,900,236 B1; EP 1,702,617 A1; US 2005/0119234 A1). JWH-073 binds to the CB1 and CB2 receptors with reported binding affinities (K_i) of 8.9 and 38.0 nM, respectively (Aung *et al.*, 2000; Wiley *et al.*, 1998).

- CB1 receptor agonists can be divided into four structural classes (1) classic cannabinoids; (2) non-classical cannabinoids; (3) aminoalkylindoles; and (4) endogenous cannabinoids (Reggio, 2003).
- 5-Fluoro-UR-144, similar to JWH-018, is a substance representative of the aminoalkylindole structural class. Aminoalkylindoles are known to exhibit typical cannabinoid pharmacology *in vivo* (D'Ambra *et al.*, 1992; Compton *et al.*, 1992).
- Furthermore, structure-activity relationship studies indicate that indole derivatives substituted with an alkyl group at the indole-1 position retain activity at the cannabinoid receptors (Huffman *et al.*, 1994; Wiley *et al.*, 1998; Aung *et al.*, 2000) and replacement of the naphthyl group by a tetramethylcyclopropyl also retains activity at the cannabinoid receptors (Frost *et al.*, 2010). 5-Fluoro-UR-144, similar to JWH-018, has the above-mentioned substitutions at the indole-1 and indole-3 positions.

Based on the anticipated receptor binding data and structure-activity relationship information, 5-fluoro-UR-144 is likely to have cannabinoid agonist properties similar to that of JWH-018.

References

- Aung MM, Griffin G, Huffman JW, Wu M-J, Keel C, Yang B, Showalter VM, Abood ME, and Martin BR (2000). **Influence of the N-1 alkyl chain length of cannabimimetic indoles upon CB1 and CB2 receptor binding.** *Drug and Alcohol Dependence* 60:133-140.
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Huffman JW, Dong D, Martin BR, and Compton DR (1994). Design, synthesis and pharmacology of cannabimimetic indoles. *Bioorganic and Medicinal Chemistry Letters* 4:563-566.

Reggio PH (2003). Pharmacophores for ligand recognition and activation/inactivation of the cannabinoid receptors. *Current Pharmaceutical Design* 9:1607-1633.

Wells DL and Ott CA (2011). The "new" marijuana. *The Annals of Pharmacotherapy* 45(3), 414-417.

Wiley JL, Compton DR, Dai D, Lainton JAH, Phillips M, Huffman JW, and Martin BR (1998). Structure activity relationships of indole- and pyrrole-derived cannabinoids. *Journal of Pharmacology and Experimental Therapeutics* 285(3):995-1004.

EP 1,702,617 A1, Makriyannis A (2006). Cannabimimetic indole derivatives (patent)

US 2005/0119234 A1, Makriyannis A and Deng H (2005). Cannabimimetic indole derivatives (patent)

US 6,900,236 B1, Markriyannis A and Deng (2005). Cannabimimetic indole derivatives (patent).

(3) 1-(5-Fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropoyl)indole (5-fluoro-UR-144; XLR11) was represented by the seller to have a pharmacological effect substantially similar to a Schedule I or II controlled substance (example: "this acts just like JWH-018"). These criteria are found at 21 U.S.C. § 802(32)(A).

The third criterion may be established from evidence collected by the investigators (example: conversations or e-mail with suspects).

Conclusion

Based on the above information, 5-fluoro-UR-144 is substantially similar in chemical structure to JWH-018 and meets the first criterion of the definition of a controlled substance analogue. Based on structure activity relationships (SAR), 5-fluoro is anticipated to have substantially similar pharmacological effects on the central nervous system as the schedule I substance, JWH-018. Depending on the individual case history, 5-fluoro-UR-144 may meet the third criterion of the definition of a controlled substance analogue. The third criterion may be established from evidence collected by the investigators (example: conversations or e-mail with suspects).

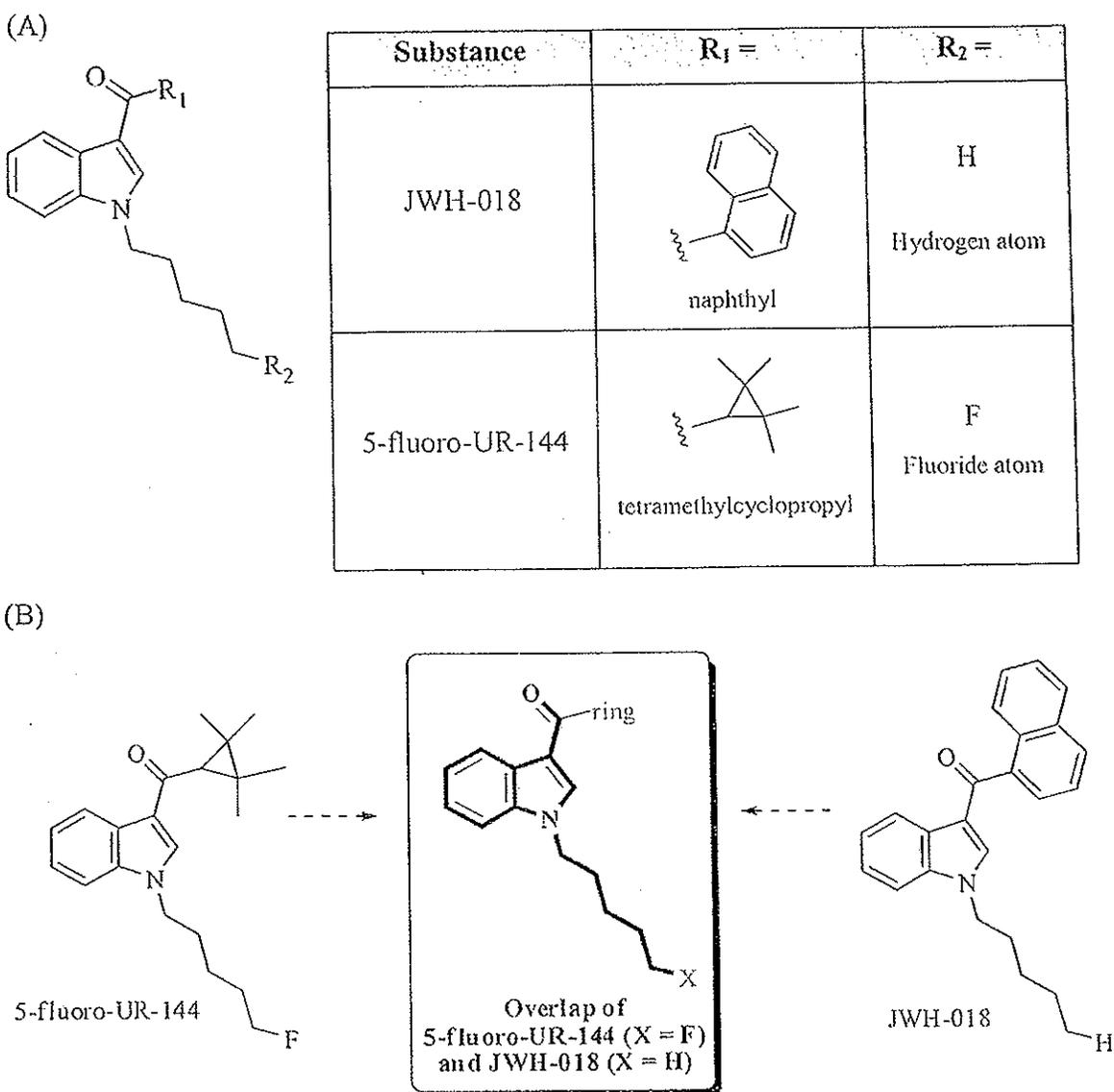


Figure 2. (A) Comparison of site specific substitution for 5-fluoro-UR-144 and JWH-018 and (B) the overlap of the two chemical structures, bold features highlight shared chemical structure.

The difference between these two substances is the ring structure attached to the 3-position the carbonyl group, alicyclic vs. aryl ring system and an atom at the terminal position of the alkyl chain. 5-Fluoro-UR-144 incorporates a tetramethylcyclopropyl ring system, whereas, JWH-018 incorporates a naphthyl ring system. At the terminal position of the alkyl chain attached to the indole-1 position is a fluoride atom in 5-fluoro-UR-144 whereas, a hydrogen atom is found at the same position in JWH-018. Other than these

OFFICE OF THE DISTRICT ATTORNEY

Brown County

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ASSISTANT DISTRICT ATTORNEYS

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John F. Luetscher
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Eric R. Enli
Thomas J. Coaty
Beau G. Liegeois
Kate R. Zuidmulder
Sarah E. Belair
Cynthia L. Vopal

November 13, 2012

Wisconsin Department of Safety and Professional Services
Controlled Substances Board
P.O. Box 8935
1400 E. Washington Avenue
Madison, WI 53708-8935

Re: Brown County Case No. 12CF1359

To Whom It May Concern:

The Brown County District Attorney's Office is currently prosecuting a case relating to the possession with intent to deliver a substance believed to be an analog of a controlled substance listed in Chapter 961 of the Wisconsin Statutes. A substance was sent to the Wisconsin State Crime Laboratory in Wausau for analysis and was given Lab Case Number W12-2040. With respect to lab case W12-2040, Analyst Michelle Gee analyzed the substance and identified the presence of a chemical substance known as (1-(5-fluoropentyl)-1H-indole-3-yl)(2,2,3,3-tetramethylcyclopropyl) methanone (XLR-11), which is not a controlled substance. (See attached Exhibit 1).

Terrence Boos, a chemist with the Drug Enforcement Administration (DEA), indicated that XLR-11 has a chemical structure substantially similar to that of JWH-018, which is a restricted controlled substance, and also has similarities of the effects on the user. (See attached Exhibit 2). In support of this position, Boos further pointed to a DEA report for XLR-11 dated May, 2012, which show the molecular similarity between XLR-11 and JWH-018 and further emphasize their similarities. (See attached Exhibit 3).

It is my understanding that the district attorney is required to provide information to this board relevant to emergency scheduling of the above-referenced substance. It is intended that this communication satisfy this office's requirements under Section 961.25, Wisconsin Statutes, and serve as a request that the Wisconsin Controlled Substance Board review XLR-11 for emergency scheduling as

contemplated under Section 961.11(4m). Please notify me of the specific procedure that needs to be followed to have this request considered or of any additional information you may require in making your determination.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Amy R.G. Pautzke". The signature is written in a cursive style with a large initial "A".

Amy R.G. Pautzke
Assistant District Attorney

ARGP/rb

Enc.



Exhibit 1

Wisconsin Department of Justice
Division of Law Enforcement Services
State Crime Laboratory - Wausau
7100 Stewart Avenue
Wausau, WI 54401-8410
(715) 845-8826
FAX (715) 848-5833

Submitting Agency:

David Poteat
Brown County Drug Task Force
P.O. Box 22082
Green Bay WI 54305-2082

Date: October 18, 2012

Lab Case: W12-2040

Agency No.: 12-0298003

Laboratory Analyst:

Michelle M. Gee 10/18/12

Michelle M. Gee

Controlled Substances Unit

Case Name: Elsner, Scott Russell (S) / Gjesdahl, Sonya L. (S) / Pate,
Jacob P. (S)

I do hereby certify this document, consisting of 1 page(s), to be a true and correct report of the findings of the State Crime Laboratory on the items examined as shown by this report. This report contains the conclusions of the above signed analyst.

J.B. Van Hollen

ATTORNEY GENERAL

[Signature]
DESIGNEE

<u>Item</u>	<u>Description / Source</u>
A	A heat-sealed plastic bag containing 1.289 grams of plant material.
B	A heat-sealed plastic bag containing 0.517 gram of plant material.
C	A heat-sealed plastic bag containing a clear and orange capsule weighing 0.194 gram.
D	A heat-sealed plastic bag containing two white round scored tablets weighing 0.525 gram.
E	A heat-sealed plastic bag containing 1.700 grams of plant material.
F	A heat-sealed plastic bag containing 1.529 grams of plant material.

Examinations of the plant material from items A and B identified the presence of Tetrahydrocannabinol, a substance from marijuana, which is controlled by Section 961.14(4)(t) of the Wisconsin Uniform Controlled Substances Act.

Examinations of the capsule from item C identified the presence of Amphetamine, which is controlled by Section 961.16(5)(a) of the Wisconsin Uniform Controlled Substances Act.

Examinations of the tablets from item D identified the presence of Lorazepam, which is controlled by Section 961.20(2)(er) of the Wisconsin Uniform Controlled Substances Act.

Examinations of the plant material from items E and F indicated the presence of (1-(5-fluoropentyl)-1H-indole-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (XLR-11).



CASE ACTIVITY REPORT

BROWN COUNTY DRUG TASK FORCE

N/I Windorff

CASE #	DATE	ACTIVITY
12-0298-006	11-02-12	Supplement

ACTIVITY: On 11-02-12, I reviewed a report from the Wisconsin State Crime Lab in reference to evidence submitted with case number #12-0298-003 in which the lab results determined that samples from Exhibits #14 and #16 contained the chemical XLR-11.

In reference to a previous case 12-0255003 dated 09-06-12, I made phone contact with Terrence Boos who is a Chemist with the Drug Enforcement Administration. The purpose of the conversation was to speak with Boos regarding the analog status of several chemicals including XLR-11.

In speaking with Boos, he advised me that it is the DEA's position that XLR-11 meets both the chemical and the pharmacological definitions of a controlled substance analog defined in the controlled substances act. Boos referred to a report on XLR-11 dated May 2012 showing the molecular similarity between XLR-11 with JWH-018 which is a restricted controlled substance and also has similarities of the effects it has on the user. (See the attached DEA report for further information).

N/I R Windorff #727

Exhibit 3

Drug Enforcement Administration
Office of Diversion Control
Drug & Chemical Evaluation Section
8701 Morrisette Drive
Springfield, Virginia 22152
(202) 307-7183

1-(5-fluoro-pentyl)-3-(2,2,3,3-
tetramethylcyclopropoyl)indole

(5-fluoro-UR-144; XLR11)

Analogue Status



May 2012

Analyse Statute of the Controlled Substances Act

The Controlled Substances Act (CSA) was amended in 1986 by enactment of the Controlled Substance Analogue Enforcement Act. This law provides for controlled substance analogues, to the extent that they are intended for human consumption, to be treated as Schedule I controlled substances for the purposes of criminal prosecution. The term "controlled substance analogue" means a substance which: (1) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II; (2) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or (3) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II. [Title 21 United States Code 802(32)(A)].

If evidence can be accumulated that the substance in question is intended for human consumption and is not already controlled under the CSA or legally marketed in the United States, the use of the analogue provision of the CSA should be considered (Title 21 United States Code 813).

(1) 1-(5-Fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropyl)indole (5-fluoro-UR-144; XLR11) shares substantial chemical structural similarities with the Schedule I substance, 1-pentyl-3-(1-naphthoyl)indole (JWH-018)

The chemical structures of 5-fluoro-UR-144 and JWH-018 are substantially similar. Both compounds share the same core indole structure as depicted in Figure 1 with substitutions at the 1 and 3 positions of this fused bi-cyclic ring system.

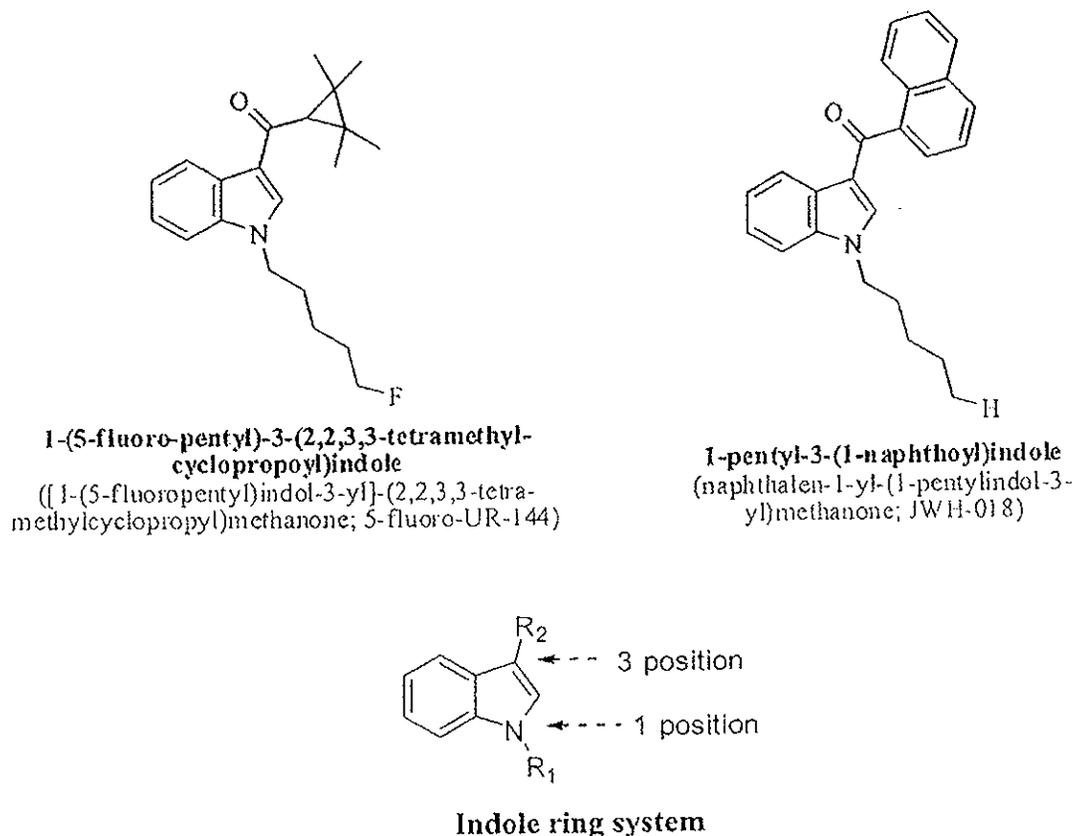


Figure 1. Structures of 5-fluoro-UR-144, JWH-018, and indole ring system

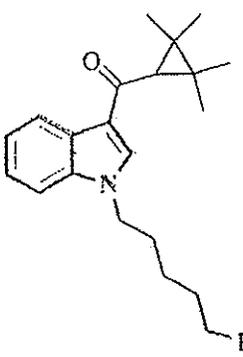
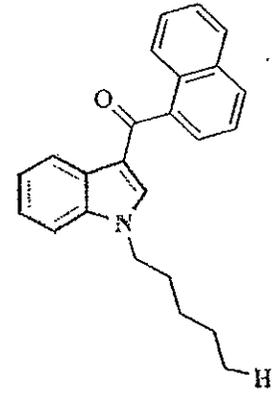
Figure 1 depicts the structures of 5-fluoro-UR-144, JWH-018, and the indole ring system. The core ring system is substituted at the indole-1 and -3 positions to give both 5-fluoro-UR-144 and JWH-018. Both substances are substituted at the 3-position with an acyl group, a carbonyl group (ketone) linked to a ring system and at the 1-position with an alkyl group, a substituted alkyl group in the case of 5-fluoro-UR-144. The alkyl group at the 1-position for both 5-fluoro-UR-144 and JWH-018 is a five carbon unit chain, known as a pentyl group and for 5-fluoro-UR-144 the terminal position of the alkyl chain is substituted with a fluoride (F) atom.

Studies concerning the aminoalkylindole structural class have focused primarily on varying the indole nitrogen and 3-position substituents. The core indole became a framework for continued investigations with the early work by Sterling-Winthrop that led to pravadoline and WIN-55212-2 (D'Ambra *et al.*, 1992). Several other groups expanded

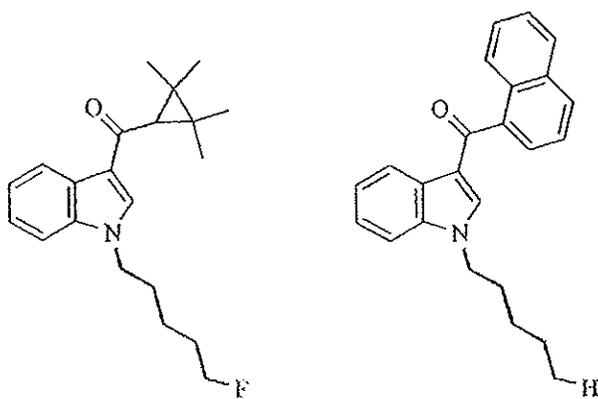
this investigation of structure activity relationships pertaining to this structural class, most notably the laboratories of Huffman and co-workers and Makriyannis and co-workers (Huffman, 2009). The scientific literature and patent literature details further substitutions of the aminoalkylindole structural class with specific substitutions at the 3-position of the indole core structure to incorporate aromatic and non-aromatic ring systems. Bell (1986) reported on the preparation of cyclohexyl ketones and the work of Frost and co-workers is an extension. A series of 3-tetramethylcyclopropyl ketone substituted indoles were prepared and evaluated (Frost *et al.*, 2008). These investigations led to the further synthesis and evaluation of nonaromatic acyl substituted substances structurally similar to 5-fluoro-UR-144 that included the substance UR-144 (Frost *et al.*, 2010).

Table 1 further highlights the structural similarities between 5-fluoro-UR-144 and JWH-018. Both substances share the core indole ring system. The nitrogen of the indole, 1-position is substituted by an alkyl moiety. Attached to the nitrogen for both 5-fluoro-UR-144 and JWH-018 is an alkyl group consisting of a five carbon chain known as a pentyl group. The terminal position of the alkyl group is substituted with a fluoride atom in 5-fluoro-UR-144, the halogen substituted alkyl group is known as a haloalkyl. The indole 3-position incorporates a carbonyl (C=O) group which is further substituted with a cyclic ring system.

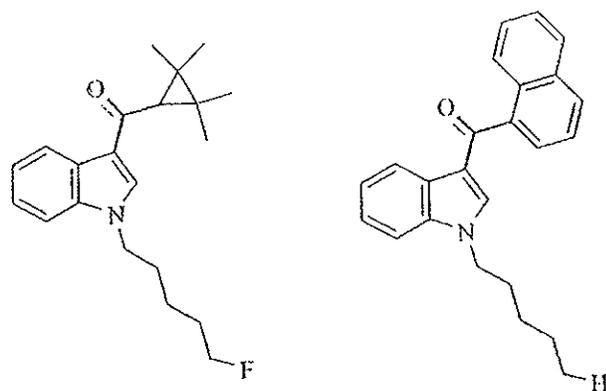
Table 1. Shared structural features

Structural feature	5-fluoro-UR-144	JWH-018
A. Indole core structure		

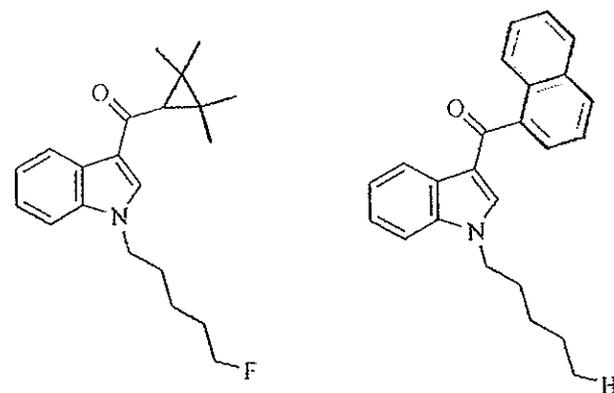
B. Indole 1-position
substitution



C. Indole 3-position
carbonyl
substitution



D. Carbonyl
substitution



The substitutions are further highlighted below with the overlap of the two chemical structures.

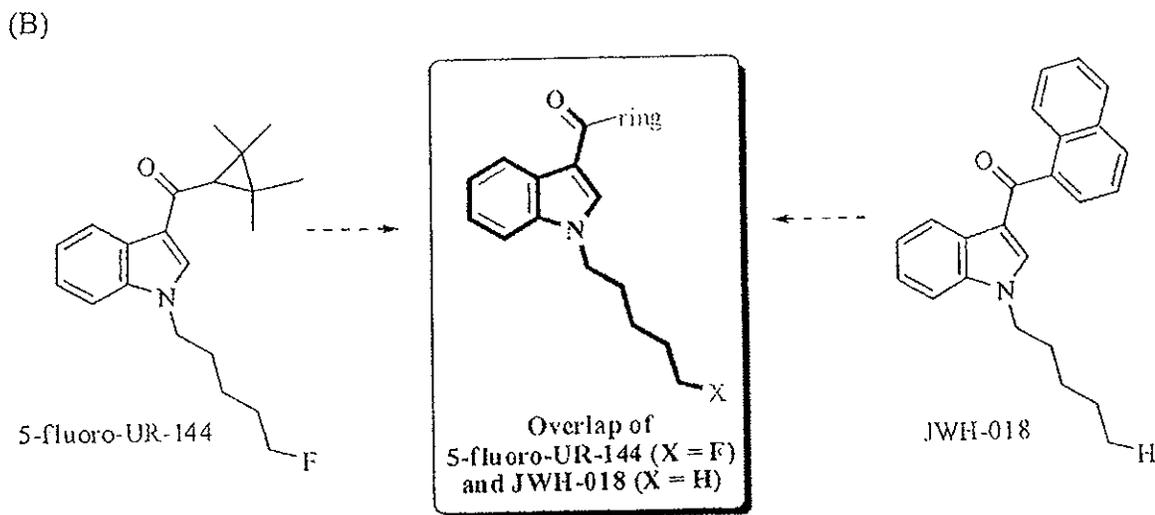
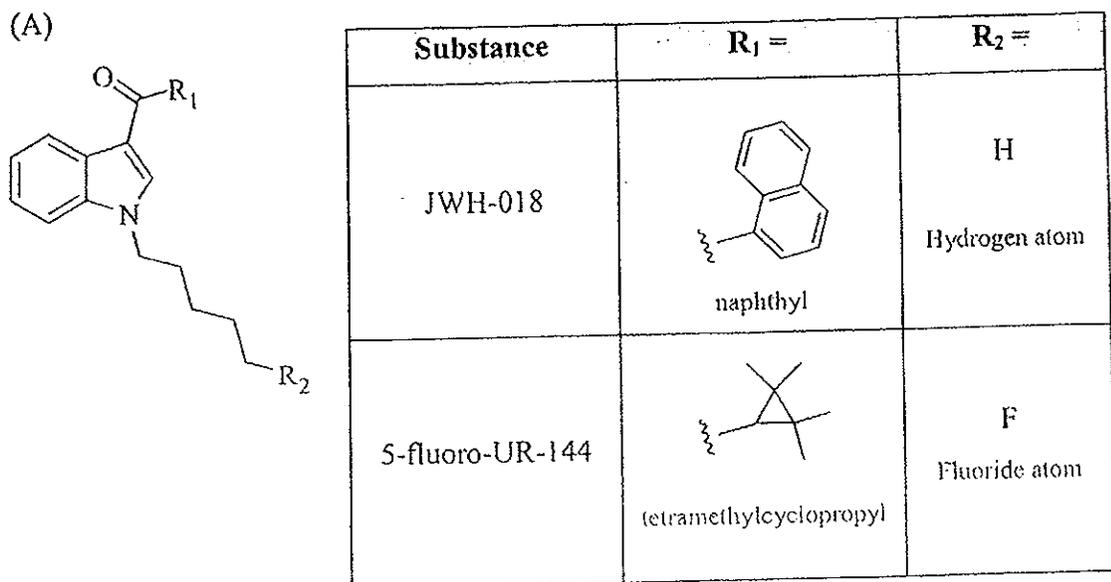


Figure 2. (A) Comparison of site specific substitution for 5-fluoro-UR-144 and JWH-018 and (B) the overlap of the two chemical structures, bold features highlight shared chemical structure.

The difference between these two substances is the ring structure attached to the 3-position the carbonyl group, alicyclic vs. aryl ring system and an atom at the terminal position of the alkyl chain. 5-Flouoro-UR-144 incorporates a tetramethylcyclopropyl ring system, whereas, JWH-018 incorporates a naphthyl ring system. At the terminal position of the alkyl chain attached to the indole-1 position is a fluoride atom in 5-fluoro-UR-144 whereas, a hydrogen atom is found at the same position in JWH-018. Other than these

differences, the remainder of the chemical structure for these two substances is the same. Therefore, based on the above analysis, 5-fluoro-UR-144 is substantially similar in chemical structure to JWH-018 and meets the first criterion of the definition of a controlled substance analogue*.

[*Note: According to 21 U.S.C. 802(32), the first criterion of the definition of a controlled substance analogue requires consideration of physical structure only. While various functional groups at different positions may alter certain physicochemical properties (solubility, polarity, melting point, etc.), these physicochemical properties are not considered in making a determination regarding structural similarity. However, they may be considered in making a determination regarding pharmacological similarity under the second criterion of the definition of an analogue.]

References

Bell MR (1986). 3-Carboxy-1-amino-1H-indoles as useful analgesics. EP171037.

D'Ambra TE, Estep KD, Bell MA, Eissenstat MA, Josef KA, Ward SJ, Haycock DA, Baizman ER, Casiano FM, Beglin NC, Chippari SM, Grego JD, Kullnig RK, and Daley GT (1992). **Conformationally restrained analogues of pravadoline: nanomolar potent, enantioselective, (aminoalkyl)indole agonists of the cannabinoid receptor.** *Journal of Medicinal Chemistry* 35, 124-135.

Frost JM, Dart MJ, Tietje KR, Garrison TR, Grayson GK, Daza AV, El-Kouhen OF, Miller LN, Li L, Yao BB, Hsieh GC, Pai M, Zhu CZ, Chandran P, and Meyer MD (2008). **Indol-3-yl-tetramethylcyclopropyl ketones: effects of indole ring substitution on CB2 cannabinoid receptor activity.** *Journal of Medicinal Chemistry*, 51:1904-1912.

Frost JM, Dart MJ, Tietje KR, Garrison TR, Grayson GK, Daza AV, El-Kouhen OF, Yao BB, Hsieh GC, Pai M, Zhu CZ, Chandran P, and Meyer MD (2010). **Indol-3-ylcycloalkyl ketones: effects of N1 substituted indole side chain variations on CB2 cannabinoid receptor activity.** *Journal of Medicinal Chemistry* 2010, 53:295-315.

Huffman JW (2009). **Cannabinimetic indoles, pyrroles, and indenenes: Structure-activity relationships and receptor interactions.** *Cannabinoid Receptors*, Reggio PH, Ed, Chapter 3, 49-98, Humana, New York

(2) 1-(5-Fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropyl)indole (5-fluoro-UR-144; XLR11) is likely to have pharmacological effects on the central nervous system that are substantially similar to that of the Schedule I substance, 1-pentyl-3-(1-naphthoyl)indole (JWH-018)

- Classical cannabinoids, such as the primary psychoactive constituent of marijuana, Δ^9 -tetrahydrocannabinol (Δ^9 -THC) produces pharmacological effects via specific receptors in the body. The complex effects of cannabinoids are considered to be mediated through at least two distinct G-protein coupled transmembrane receptors designated as CB1 and CB2. The CB1 receptors are found predominately in the central nervous system, and are attributed to most of the overt pharmacological effects of cannabinoids. The CB1 receptors are thought to be responsible for the euphoric and psychoactive effects (Wells and Ott, 2011). The CB2 receptors are found primarily in the periphery and expressed in the immune system.
- UR-144, a close structural congener of 5-fluoro-UR-144 differing only by lacking the fluoride atom on the alkyl chain, binds to both CB1 and CB2 receptors with reported binding affinities (K_i) of 150 and 1.8 nM, respectively (Frost *et al.*, 2010). JWH-018 binds to the CB1 and CB2 receptors with reported binding affinities (K_i) of 9.0 and 2.9 nM, respectively (Aung *et al.*, 2000; Wiley *et al.*, 1998).
- Based on trends from similar modifications (example AM-2201 vs. JWH-018), the substitution of a fluoride atom on the terminal position of the five carbon alkyl chain (pentyl) is well tolerated. Thus it would be anticipated that the substitution of a fluoride atom on the alkyl chain of UR-144 would retain similar binding affinity for the CB1 receptor.
 - Examples of fluoride atom substitution on binding affinity
 - AM-2201 binds to both CB1 and CB2 receptors with reported binding affinities (K_i) of 1.0 and 2.6 nM, respectively (US 6,900,236 B1; EP 1,702,617 A1; US 2005/0119234 A1). JWH-018 binds to the CB1 and CB2 receptors with reported binding affinities (K_i) of 9.0 and 2.9 nM, respectively (Aung *et al.*, 2000; Wiley *et al.*, 1998).
 - AM1248 binds to both CB1 and CB2 receptors with reported binding affinities (K_i) of 1.3 and 10.5 nM, respectively (US

6,900,236 B1; EP 1,702,617 A1; US 2005/0119234 A1). JWH-073 binds to the CB1 and CB2 receptors with reported binding affinities (K_i) of 8.9 and 38.0 nM, respectively (Aung *et al.*, 2000; Wiley *et al.*, 1998).

- CB1 receptor agonists can be divided into four structural classes (1) classic cannabinoids; (2) non-classical cannabinoids; (3) aminoalkylindoles; and (4) endogenous cannabinoids (Reggio, 2003).
- 5-Fluoro-UR-144, similar to JWH-018, is a substance representative of the aminoalkylindole structural class. Aminoalkylindoles are known to exhibit typical cannabinoid pharmacology *in vivo* (D'Ambra *et al.*, 1992; Compton *et al.*, 1992).
- Furthermore, structure-activity relationship studies indicate that indole derivatives substituted with an alkyl group at the indole-1 position retain activity at the cannabinoid receptors (Huffman *et al.*, 1994; Wiley *et al.*, 1998; Aung *et al.*, 2000) and replacement of the naphthyl group by a tetramethylcyclopropyl also retains activity at the cannabinoid receptors (Frost *et al.*, 2010). 5-Fluoro-UR-144, similar to JWH-018, has the above-mentioned substitutions at the indole-1 and indole-3 positions.

Based on the anticipated receptor binding data and structure-activity relationship information, 5-fluoro-UR-144 is likely to have cannabinoid agonist properties similar to that of JWH-018.

References

Aung MM, Griffin G, Huffinan JW, Wu M-J, Keel C, Yang B, Showalter VM, Abood ME, and Martin BR (2000). **Influence of the N-1 alkyl chain length of cannabimimetic indoles upon CB1 and CB2 receptor binding.** *Drug and Alcohol Dependence* 60:133-140.

Compton DR, Gold LH, Ward SJ, Baister RL, and Martin BR (1992). **Aminoalkylindole analogs: cannabimimetic activity of a class of compounds structurally distinct from Δ^9 -Tetrahydrocannabinol.** *Journal of Pharmacology and Experimental Therapeutics* 263(3): 1118-1126.

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of pravadoline: nanomolar potent, enantioselective, (aminoalkyl)indole agonists of the cannabinoid receptor. *Journal of Medicinal Chemistry* 35(1):124-135.

Frost JM, Dart MJ, Tietje KR, Garrison TR, Grayson GK, Daza AV, El-Kouhen OF, Yao BB, Hsieh GC, Pai M, Zhu CZ, Chandran P, and Meyer MD (2010). **Indol-3-ylcycloalkyl ketones: effects of N1 substituted indole side chain variations on CB2 cannabinoid receptor activity.** *Journal of Medicinal Chemistry* 2010, 53:295-315.

Huffman JW, Dong D, Martin BR, and Compton DR (1994). **Design, synthesis and pharmacology of cannabimimetic indoles.** *Bioorganic and Medicinal Chemistry Letters* 4:563-566.

Reggio PH (2003). **Pharmacophores for ligand recognition and activation/inactivation of the cannabinoid receptors.** *Current Pharmaceutical Design* 9:1607-1633.

Wells DL and Ott CA (2011). The "new" marijuana. *The Annals of Pharmacotherapy* 45(3), 414-417.

Wiley JL, Compton DR, Dai D, Lainton JAH, Phillips M, Huffman JW, and Martin BR (1998). **Structure activity relationships of indole- and pyrrole-derived cannabinoids.** *Journal of Pharmacology and Experimental Therapeutics* 285(3):995-1004.

EP 1,702,617 A1, Makriyannis A (2006). Cannabimimetic indole derivatives (patent)

US 2005/0119234 A1, Makriyannis A and Deng H (2005). Cannabimimetic indole derivatives (patent)

US 6,900,236 B1, Markriyannis A and Deng (2005). Cannabimimetic indole derivatives (patent).

(3) 1-(5-Fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropoyl)indole (5-fluoro-UR-144; XLR11) was represented by the seller to have a pharmacological effect substantially similar to a Schedule I or II controlled substance (example: "this acts just like JWH-018"). These criteria are found at 21 U.S.C. § 802(32)(A).

The third criterion may be established from evidence collected by the investigators (example: conversations or e-mail with suspects).

Conclusion

Based on the above information, 5-fluoro-UR-144 is substantially similar in chemical structure to JWH-018 and meets the first criterion of the definition of a controlled substance analogue. Based on structure activity relationships (SAR), 5-fluoro is anticipated to have substantially similar pharmacological effects on the central nervous system as the schedule I substance, JWH-018. Depending on the individual case history, 5-fluoro-UR-144 may meet the third criterion of the definition of a controlled substance analogue. The third criterion may be established from evidence collected by the investigators (example: conversations or e-mail with suspects).

Dan,

A couple of questions have come up about the new SUA rules which just became effective November 1st (CSB 3.0)...

1. Are DEA exempt analytical standard reference materials included in the requirement to amend an SUA under CSB 3.04(6)(b)?

These reference standards are sold by a variety of vendors (Cerilliant, Alltech, etc.) and are typically one milliliter of solvent containing one milligram of a controlled substance, or less.

2. CSB 3.04(6)(b) discusses a situation where an analytical lab “purchases or otherwise adds to its inventory a new controlled substance or an additional amount of a controlled substance that was not previously authorized in a permit”. Does CSB 3.04(6)(b) conflict with CSB 3.06(2) and CSB 3.08(1)(a)? Can an analytical lab add controlled substances to its inventory prior to amending its SUA?

Also, to follow up on my previous comments regarding scheduling actions by the DEA, I put together a document (attached) which lists current Federally controlled substances which are not listed in the Wisconsin Controlled Substances Act. I have included “suggested” WI scheduling locations that would be consistent with the Federal Schedules. Included as well, is a listing of all the substances controlled Federally (including chemical name) as part of the legislation signed this past summer (S. 3187).

Marty

Martin G. Koch
Forensic Scientist
Controlled Substances Unit
Wisconsin State Crime Laboratory
Madison, WI 53705-2156
Voice: (608)266-2031
Fax: (608)267-1303

From: Koch, Martin G. [<mailto:kochmg@DOJ.STATE.WI.US>]
Sent: Thursday, October 18, 2012 4:51 PM
To: Williams, Dan - DSPS
Subject: RE: CSB Assistance

Dan,

This is an extraordinarily complicated issue. I'll do my best to be brief, however, I do think a wider discussion, as a board, needs to occur on the overall issue of analogs.

This is not by any means a new issue. Dealing with the prosecution of controlled substance analogs has always been extraordinarily difficult in Wisconsin. Unfortunately, placing the term “analog” into Sections 961.14(4) and (7) has not really assisted prosecutors. It has actually caused a great deal of confusion. Confusion exists due to the lack of a statutory definition for “analog”. As a chemist, I may have an opinion as to what an “analog” is, however, as Doug stated, not all chemists may share that same opinion. For this reason, prosecutors are more likely to use the definition given in Section 961.01(4m).

At the lab, when asked for advice regarding analog prosecutions, we have always steered prosecutors to the language of Section 961.01(4m). This Brown County prosecutor is clearly acting on this language. In a nutshell, as I understand this, he/she will need the CSB to emergency schedule the substance, a Crime Lab chemist to testify to the identity and structural similarity of the substance, and in addition, a second expert (pharmacologist/toxicologist?) to testify to the physiological effects of the substance.

The Crime Lab does have forensic chemists (such as myself) available to analyze and testify to the chemistry portion, however, we do not have staff members with the requisite background in pharmacology. The DEA does have both forensic chemists and pharmacologists on staff. These are the person(s) who likely prepared the “analog” documents which you had attached to your original email.

I agree with the DEA. UR-144 and XLR-11 are substantially similar in chemical structure to JWH-018. I am not in a position to opine as to physiological effects of either UR-144, or XLR-11.

I would be supportive for the emergency scheduling of UR-144 and XLR-11.

In July of this year (2012) President Obama signed Senate Bill 3187 (Food and Drug Administration Safety and Innovation Act) which federally controls the following synthetic cannabinoids and designer hallucinogens:

JWH-019
JWH-122
JWH-398
AM2201
AM694
RCS-4
RCS-8
JWH-203
2C-E
2C-D
2C-C
2C-T-2
2C-T-4
2C-H
2C-H
2C-N
2C-P

The board should consider beginning the rule making process to add these to Chapter 961. Emergency scheduling of these recently federally controlled substances would allow these substances to be prohibited while the board is engaged in the rule making process.

Marty

State of Wisconsin Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Dan Williams		2) Date When Request Submitted: 11/23/12 <small>Items will be considered late if submitted after 4:30 p.m. and less than:</small> <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: WI Controlled Substances Board			
4) Meeting Date: 12/11/12	5) Attachments: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	6) How should the item be titled on the agenda page? Report as to the Presentation at the Wisconsin Federated Humane Societies Badger States Conference	
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: Same as title From: Pam McCloud Smith [mailto:pmsmith@giveshelter.org] Sent: Thursday, March 29, 2012 9:21 PM To: Bellay, Yvonne M - DATCP Subject: Request for Special Use Authorization Presentation Hi Dr. Bellay, I'd like to submit this formal request for you to give a presentation on the Special Use Authorization relating to animal shelter's at our Wisconsin Federated Humane Societies Badger States Conference on October 11, 2012 from 3:00-5:00 p.m. at the Holiday Inn & Convention Center in Stevens Point, Wisconsin. Please let me know if you have any questions. Thank you for your consideration. I look forward to hearing back from you. Pam McCloud Smith Wisconsin Federated Humane Societies, Board Treasurer President Elect 5/10/12 .			
11) Authorization			
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 Board Services Bureau Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Executive Assistant prior to the start of a meeting.			

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

AGENDA REQUEST FORM

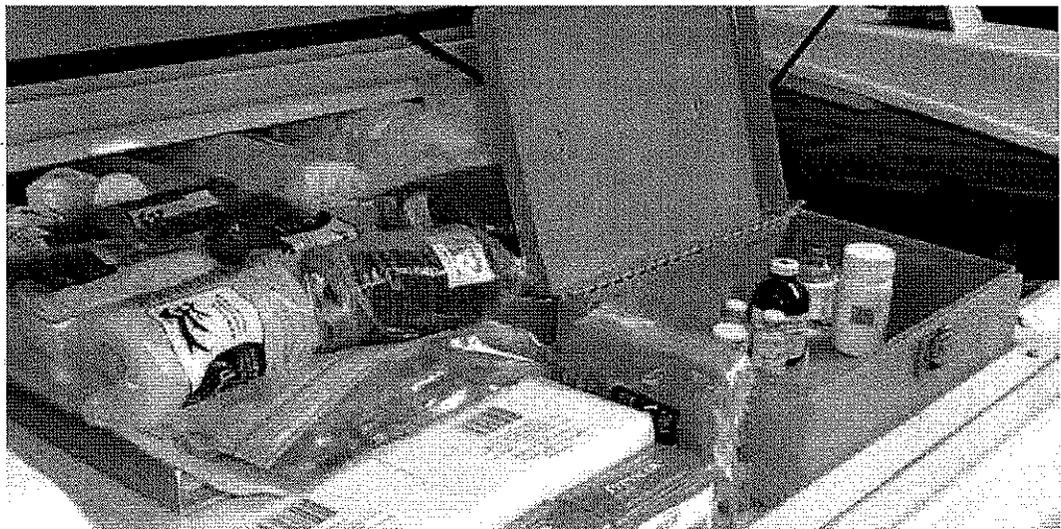
1) Name and Title of Person Submitting the Request: Dan Williams		2) Date When Request Submitted: 11/23/12 Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: WI Controlled Substances Board			
4) Meeting Date: 12/11/12	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Discussion and consideration of JAVMA article re: Vets mobile practice	
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 checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: See attached article from the JAVMA newsletter.			
11) Authorization			
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 Board Services Bureau Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Executive Assistant prior to the start of a meeting.			



JAVMAnews

PRACTICE

Federal law could affect mobile practice Veterinarians express concern over drug acc



This photo shows a lockbox used to transport controlled substances inside a California veterinarian's truck.

Posted on May 30, 2012

By Greg Cima

Dr. Lisa S. Couper isn't allowed to carry some drugs she sees as essential for her mobile mixed animal practice.

She is among Northern California veterinarians with ambulatory or mobile practices who said Drug Enforcement Administration federal law if they routinely carry controlled substances in their vehicles.

"I wasn't aware that it was against the code until now," she said. "Now that I am, what do I do? What are the DEA's intentions? If they really are intent on enforcing, I'm going to have to call it quits."

Barbara L. Carreno, a spokeswoman for the DEA, said the federal Controlled Substances Act, which Congress passed in 1962, requires veterinarians, physicians, and dentists—have separate registrations for every location where they store, distribute, or dispense controlled substances. Practitioners in human and veterinary medicine register in one location and prescribe controlled substances in others, and so do they have an allowance.

Dr. Grant R. Miller, director of regulatory affairs for the California VMA and a veterinarian whose patients include horses, cats, and dogs, said that veterinarians would be allowed to bring the amount of a drug they intend to use during the day, although that allowance would be limited.

"They're saying you can't take these things out in the field and use them without having some kind of preset amount that you can use," he said.

Dr. Miller said that would, for example, allow a veterinarian carry the drugs needed for a previously scheduled appointment, but he interprets the allowance to mean that a veterinarian would not be able to carry controlled substances for use in an emergency. He said he would conduct a one-day spay and neuter clinic at a rural pet store, where the numbers and sizes of animals arriving would be unknown.

On the basis of reports from California VMA members, Dr. Miller said it appeared that officials in a DEA office in Sacramento were using their home address as their place of business. The VMA posted on its website a copy of a letter that states a DEA official was asked to provide their business addresses. By early May, the VMA was receiving eight or 10 calls daily from veterinarians concerned about the DEA's actions, which tapered to a few weekly by mid-May.

Dr. Couper said her mobile practice has been registered at her home address for the past 25 years. In responding to one of the DEA's letters, she said she was allowed to treat patients or dispense controlled substances there, but she was told that her mobile clinic had been transported to another location.

Notice issued over confusion

Back on Dec. 1, 2006, the DEA published a Federal Register notice intended to alleviate confusion over the agency's rules regarding controlled substances for practitioners, including veterinarians. In addition to stating that practitioners can store, administer, or dispense controlled substances, the notice states that practitioners need a separate registration for each state where they prescribe a controlled substance. The notice was issued under federal regulations.

"The Controlled Substances Act would have to be amended by Congress to do that because our regulations implement the law and we don't have the authority to change it," Carreno said.

Violating the Controlled Substances Act can result in various penalties, depending on the circumstances of each violation, including sending a letter to admonish a registrant that he or she was violating the law, initiating proceedings to withdraw DEA registration, or threatening, suspending the individual's registration, according to an August 2011 Government Accountability Office report.

Practitioners can face civil penalties such as fines for violating record-keeping requirements for controlled substances. More serious offenses, such as fraud, tax evasion, and money laundering, can result in criminal charges, according to the GAO report.

In a letter sent to the DEA April 30, 2012, Dr. Ron DeHaven, AVMA CEO, asked the DEA to exercise enforcement discretion for veterinarians who hold valid state licenses and DEA registrations.

His letter indicates many AVMA members, particularly those in rural and large animal practices, provide mobile or ambulatory services and easily bring their animals to a clinic or hospital. Many companion animal veterinarians also provide house call services and can provide emergency care.

Dr. DeHaven's letter expresses support for the intent of the DEA Diversion Control Program but expresses concern that enforcing existing regulations on veterinarians to comply with the regulations while providing their patients with appropriate and complete veterinary care and

The letter notes that the AVMA has been meeting with DEA officials since 2009 to address the regulations and has been told Controlled Substances Act to change the current regulations to address the AVMA's concerns.

Dr. M. Gatz Riddell, executive vice president of the American Association of Bovine Practitioners, noted that not all veterinarian clients can deliver their animals to a clinic or hospital. He indicated that enforcement of the existing regulations could hinder provide analgesia for their patients in the field.

"It would really impede a veterinarian's ability to provide for the prevention of pain and suffering of their patients in certain co

Rising concern, changing practice

Dr. Thomas W. Graham of Davis, Calif., stopped carrying pentobarbital, diazepam, xylazine, and butorphanol in his vehicle illegal. He intends to comply with all directions from the DEA, and he fears penalties could result if he were to fail to follow th a DEA inspection or a state police traffic stop. He thinks agency officials are trying to do what is best to implement a law stru

Dr. Graham, who is a bovine practitioner, said, however, some alternatives to controlled substances are less reliable for prov

"I have a surgery today that I'm supposed to do to remove an eye in a cow, and I guess I'll just use lidocaine," Dr. Graham s:

Dr. Miller noted that, even if he is allowed to carry amounts of controlled substances intended for use, he often would need to amount of pain it was in, and the severity of its condition before he could know how much of any particular drug was needed for euthanasia could be insufficient if an animal were agitated, he said.

"We couldn't have an extra supply on hand in the field when we're euthanizing an animal," he said.

Dr. Couper said she has an ethical obligation to carry proper drugs to care for her patients, but following the rules as they we carry sufficient amounts of controlled substances to re-sedate an animal, if needed, or adapt in situations involving spilled dr

Dr. Graham hopes congressional involvement isn't needed. For now, he uses a .22 Magnum handgun for euthanasia, and h assurances that the practice is legal.

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