VETERINARY EXAMINING BOARD

Open Session Conference Line: 1-855-947-8255
Passcode: 8463633#

Contact: Melissa Mace 608-279-3861
July 29, 2020

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 record of the actions of the Board.

AGENDA

I. 9:00 A.M. OPEN SESSION – CALL TO ORDER – ROLL CALL

II. Introductions
A. Amanda Reese – new appointee filling the Public Member position previously occupied by Bruce Berth.

III. Approval of the Agenda

IV. Approval of Board Meeting Minutes
A. April 29, 2020

V. Public Comments
Each speaker is limited to five minutes or less, depending on the number of speakers. Each speaker must fill out and submit an appearance card to the Board clerk.

VI. American Association of Veterinary State Boards (AAVSB) Matters
A. Annual Meeting Portland Oregon September 24-26 – In person aspects canceled.

VII. Board Guidance
A. Comments and Consideration for Adoption
1. Bull Semen Collection
2. Cannabis

VIII. Licensing/Exam Inquiries
A. License numbers for 20-21 licensing year
B. Processes that expedited licensing during COVID:
1. Waiver
2. AAVSB

IX. Administrative Code Items

A. VE 1-11 – Reorganization – Board Approval of Preliminary Public Hearing and Comment Period

X. Legislative Update

XI. Administrative Items

A. COVID 19
B. Strategic Planning 2021

XII. Future Meeting Dates and Times

A. October 21, 2020

XIII. CONVENE TO CLOSED SESSION

CONVENE TO CLOSED SESSION to discuss the Wis. Admin. Code ch. VE 11 update on the request for proposals where bargaining reasons require a closed session (§ 19.85 (1) (e), Stats.); to deliberate on cases following hearing (§ 19.85 (1) (a), Stats.); to consider licensure or certification of individuals (§ 19.85 (1) (b), Stats.); to consider closing disciplinary investigations with administrative warnings (§ 19.85 (1) (b), Stats.); to consider individual histories or disciplinary data (§ 19.85 (1) (f), Stats.); and to confer with legal counsel (§ 19.85 (1) (g), Stats.).

XIV. Wis. Admin. Code Ch. VE 11 Update on the Request for Proposals (RFP)

XV. Deliberation on Licenses and Certificates

XVI. Deliberation on Proposed Stipulations, Final Decisions and Orders

A. 17 VET 023 JK
B. 17 VET 041 MS
C. 19 VET 013 RK
D. 19 VET 054 RW
E. 19 VET 087 CJ
F. 19 VET 108 CK
G. 20 VET 011 JS

XVII. Review of Veterinary Examining Board Pending Cases Status Report

XVIII. RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION
Open Session Conference Line: 1-855-947-8255 Passcode: 8463633#

XIX. Open Session Items Noticed Above not Completed in the Initial Open Session

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

XXI. Ratification of Licenses and Certificates

To delegate ratification of examination results to DATCP staff and to ratify all licenses and certificates as issued.

XXII. ADJOURNMENT

The Board may break for lunch sometime during the meeting and reconvene shortly thereafter.

VETERINARY EXAMINING BOARD

MEETING MINUTES

Wednesday, April 29, 2020

MEMBERS PRESENT: Bruce Berth; Diane Dommer Martin, DVM; Robert Forbes, DVM; Kevin Kreier, DVM; Hunter Lang, DVM; Lyn Schuh; Arden Sherpe; Lisa Weisensel Nesson, DVM.

STAFF PRESENT, Department of Agriculture, Trade and Consumer Protection (DATCP): Melissa Mace, VEB Executive Director; Cheryl Daniels and Liz Kennebeck, DATCP Attorneys; Robert Van Lanen, Regulatory Specialist; Angela Fisher, Program and Policy Analyst; Carrie Saynisch, License/Permit Program Associate; Karen Torvell, Program Assistant Supervisor; Dustin Boyd, Compliance Supervisor; Brittany Medina; Introductions and Discussion.

Robert Forbes, Chair, called the meeting to order at 9:04AM. A quorum of eight (8) members was confirmed.

AGENDA

I. 9:00 A.M. OPEN SESSION – CALL TO ORDER – ROLL CALL

II. Introductions

III. Approval of the Agenda

MOTION: Lisa Weisensel Nesson moved, seconded by Hunter Lang, to approve the agenda. Motion carried unanimously.

IV. Approval of Board Meeting Minutes

A. Full Board January 22, 2020

B. Credentialing Committee February 19, 2020

MOTION: Kevin Kreier moved, seconded by Lisa Weisensel Nesson, to approve the minutes from the January 22, 2020 VEB meeting and the minutes from the February 19, 2020 Credentialing Committee meeting. Motion carried unanimously.

V. Public Comments

Each speaker is limited to five minutes or less, depending on the number of speakers. Each speaker must fill out and submit an appearance card to the Board clerk.

Jordan Lamb said thank you for DATCP staff for their responsiveness over the past few weeks.

VI. American Association of Veterinary State Boards (AAVSB) Matters

A. Board Basics & Beyond Training
The April event was postponed for August 14th and 15th.

B. NAVLE Self-Assessment option
Board members can take it to see what NAVLE looks like currently.

C. AAVSB Call for Nomination
Four positions are open and seeking nominations. Nominations are due May 28th. Elections will occur at the annual meeting.

D. Annual Meeting Portland, Oregon September 24-26
~~This may be~~T ~~-~~the Executive Director and Board Chair are currently planning to attending in the event they have a strategic planning seminar. Others who are interested are encourage to put their names forward.

VII. Board Guidance

VIII. Administrative Items

A. COVID-19 response
DATCP staff worked with the Wisconsin Veterinary Medical Association (WVMA) to get information out about the Safer at Home order.
The Board encouraged the use of telemedicine where a VCPR exists, and relaxed rules regarding the frequency of physical exams and visits to the premises to maintain a VCPR, but did not allow for a VCPR to be established using a telemedicine.
The order is a Department of Health Services (DHS) order and is not interpreted or enforced by DATCP or the VEB. Veterinary practice is an essential service under the order. Veterinarians should limit activities to essential services. Veterinarians need to use their discretion about what services are essential and what can be done with relative safety using telemedicine. What may not have been essential a month ago may become essential as times goes on.
DHS and DATCP sent out a joint communication regarding the testing of animals. The agencies are not recommending testing of animals for COVID-19.

IX. Licensing/Exam Inquiries

A. Addresses on licenses
A statute regarding the Pharmacy Board requires that wholesale drug distributors can only distribute to the address on the veterinarian's license. Previously, VEB licenses only recorded the license holder's residential address, because the VEB licenses the individual and not the clinic/business. DATCP is working on a process to allow license holders to add a clinic address ~~on~~ to their license file through the web portal.

X. Administrative Code Items (No items require board action – for information only)

A. Rule Status': VE 7 (CAITs) and VE 1-11 (Reorg and Telehealth)
The VE 7 CAITs final rule was published in the March register and effective April 1, 2020. The VE 1-11 statement of scope was revised to include telehealth. The revised scope was submitted to the governor for approval. After the governor approves, the scope will go to both the VEB and DATCP Board for approval. If JCRAR requires an additional preliminary hearing, the notice of the public hearing would need to be approved by both Boards, the hearing and comment period would be held, and then the Boards could each approve the statement of scope.

XI. Legislative Update (No items require board action – for information only)

A. Passed: 2019 Wisconsin Act 143
Streamlines the process for reciprocal credentials.

B. Failed Bills: AB 130; SB 915; AB 851

XII. Future Meeting Dates and Times

A. July 29, 2020
B. October 21, 2020

XIII. CONVENE TO CLOSED SESSION

MOTION: Lisa Weisensel Nesson moved, seconded by Diane Dommer Martin, to convene to closed session to discuss the Wis. Admin. Code Ch. VE 11 update on the request for proposals where bargaining reasons require a closed session (§ 19.85 (1) (e), Stats.); to deliberate on cases following hearing (§ 19.85 (1) (a), Stats.); to consider licensure or certification of individuals (§ 19.85 (1) (b), Stats.); to consider closing disciplinary investigations with administrative warnings (§ 19.85 (1) (b), Stats.); to consider individual histories or disciplinary data (§ 19.85 (1) (f), Stats.); and to confer with legal counsel (§ 19.85 (1) (g), Stats.). Robert Forbes read the language of the motion. The vote of each member by was ascertained by voice vote. Roll Call Vote: Robert Forbes – yes; Kevin Kreier – yes; Diane Dommer Martin – yes; Hunter Lang – yes; Bruce Berth – yes; Lisa Weisensel Nesson – yes; Lyn Schuh – yes; Arden Sherpe – yes; Motion carried unanimously.

XIV. Wis. Admin. Code Ch. VE 11 Update on the Request for Proposals (RFP)

XV. Deliberation on Licenses and Certificates

A. Credentialing - NP

XVI. Deliberation on Proposed Stipulations, Final Decisions and Orders

A. 17 VET 023 JH
B. 17 VET 040 BR
C. 17 VET 041 MS
D. 18 VET 017 EP
E. 19 VET 001 SL

F. 19 VET 030 MM
G. 19 VET 059 PD
H. 19 VET 066 SR
I. 19 VET 070 MH

XVII. Review of Veterinary Examining Board Pending Cases Status Report

XVIII. RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

MOTION: Bruce Berth moved, seconded by Lisa Weisensel Nesson, to reconvene to open session. Motion carried unanimously. The Board reconvened at 10:49AM.

XIX. Open Session Items Noticed Above not Completed in the Initial Open Session

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

MOTION: Arden Sherpe moved, seconded by Kevin Kreier, to direct DATCP staff to create a limited license for NP to be reviewed by the credentialing committee and including quarterly testing through 2021 and therapy sessions. Motion carried unanimously.

MOTION: Kevin Kreier moved, seconded by Diane Dommer Martin, to approve administrative warnings for 17 VET 023 JH, 19 VET 030 MM, and 19 VET 066 SR. Motion carried unanimously.

MOTION: Hunter Lang moved, seconded by Kevin Kreier, to approve orders granting full licensure and final decision orders for 17 VET 040 BR, 17 VET 041 MS, 18 VET 017 EP, 19 VET 001 SL, 19 VET 059 PD, 17 VET 070 MH. Motion carried unanimously.

XXI. Ratification of Licenses and Certificates

MOTION: Lisa Weisensel Nesson moved, seconded by Kevin Kreier, to delegate ratification of examination results to DATCP staff and to ratify all licenses and certificates as issued. Motion carried unanimously.

XXII. ADJOURNMENT

MOTION: Lisa Weisensel Nesson moved, seconded by Kevin Kreier, to adjourn. Motion carried unanimously.

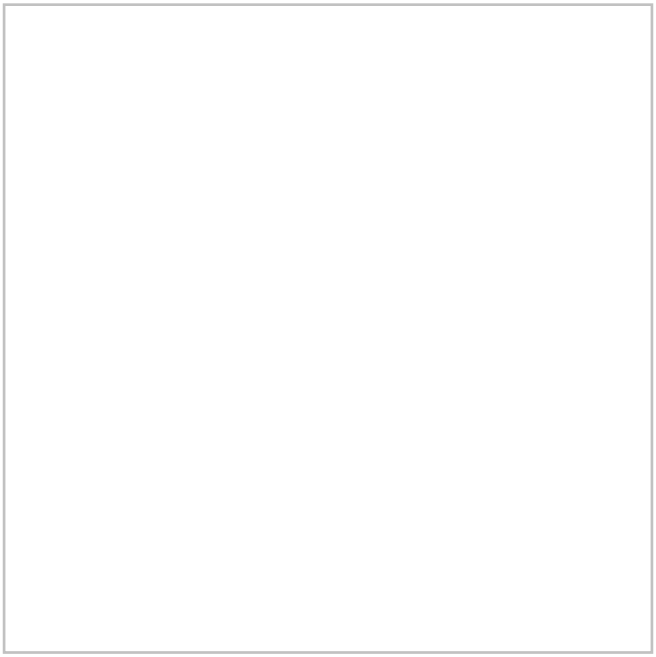
The meeting adjourned at 10:58AM.

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	
2) Requestor Name	
3) Item Title for the Agenda	
4) Should the Item be in Open or Closed Session?	
5) Are there Attachments? (If yes, include file names)	
6) Is a Public Appearance Anticipated?	
7) Description of the Agenda Item	

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	7/29/20
2) Requestor Name	Melissa Mace
3) Item Title for the Agenda	AAVSB annual meeting attendees
4) Should the Item be in Open or Closed Session?	Open
5) Are there Attachments? (If yes, include file names)	https://aavsb.org/board-services/annual-meeting/
6) Is a Public Appearance Anticipated?	No
7) Description of the Agenda Item	September 24-26, 2020 for the 2020 AAVSB Annual Meeting in Conference to be held inPortland, Oregon at The Nines Hotel Verify if they will be having the Strategic Planning session prior to the meeting for the Chair and ED. Who else is going?



2020 AAVSB ANNUAL MEETING & CONFERENCE UPDATE

Dear Melissa,

I am writing to provide an update on the 2020 Annual Meeting & Conference. As you know, the Annual Meeting has two components – the Educational Meeting and the Annual Delegate Assembly. Several factors were considered when the AAVSB Board of Directors discussed this year's meeting including the COVID-19 pandemic, executive orders for the scheduled location of Portland, Oregon, and the results from the membership survey on the meeting.

Educational Meeting
In this complicated time, the AAVSB Board of Directors feel it is imperative our community engages with and learns from one another. Each Member Board has individually worked through the pandemic and has great knowledge to share. For those reasons, the Educational Meeting will be held virtually. This ensures you receive regulatory education and have a chance to interact with other Member Boards as we all continue the important task of regulating the veterinary profession. These education sessions will be submitted for RACE® approved credit. Taking into account your time and video conferencing overload, the schedule will be designed over several months with 1 – 1.5-hour sessions approximately twice per month. We look forward to your engagement in these virtual offerings.

Annual Delegate Assembly
The other component of the Annual Conference, the Delegate Assembly,

will be cancelled for 2020. The Board of Directors feels there are three important reasons for the cancellation including:

- The business session of the Association lends itself to Delegates and members being face-to- face.
- Achieving quorum would be difficult through virtual means.
- Continuity of leadership is extremely important during these unprecedented times.

The cancellation of the Delegate Assembly impacts voting on proposed Bylaws amendments as well as elections for the open positions. Per the AAVSB bylaws, the current members of the Board of Directors, the Nominating Committee, and the Representatives to the ICVA, shall serve "until a successor is elected and qualified" which will occur at the 2021 AAVSB Annual Meeting & Conference in Denver, Colorado on September 30 – October 2. Submitted proposed Bylaws amendments will be deferred until 2021.

I thank you for your understanding of the changes for the 2020 AAVSB Annual Meeting & Conference. I look forward to continuing my service to you into 2021. If you have any concerns, please feel free to contact me directly at President@aavsb.org.

Sincerely,

Roger Redman, DVM
AAVSB President
President@aavsb.org

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Veterinary Examining Board
Agenda Request Form

1) Meeting Date	4/29/20
2) Requestor Name	Angela Fisher
3) Item Title for the Agenda	Guidance Document – Comments and Consideration for Adoption - Bull Semen Collection
4) Should the Item be in Open or Closed Session?	Open
5) Are there Attachments? (If yes, include file names)	"VEB-GD-001 Bull Semen Collection"
6) Is a Public Appearance Anticipated?	No
7) Description of the Agenda Item	**This guidance document has been posted for the required comment period. No comments were received. At this meeting the guidance document will be considered for official adoption.** Wis. Stat. s. 227.112 (1) requires the Board to: - Post a proposed guidance document on the agency website (VEB-GD-001 was posted on 11/6/19) - Post a proposed guidance document in the Administrative Register with a comment period of at least 21 days (VEB-GD-001 was posted on 11/11/19) - Consider comments in determining whether to adopt the guidance document as originally proposed, modify the proposed guidance document, or take any other action. (No comments were received.) Modifying and/or adopting the guidance document will require a motion by the Board. After adoption, the guidance document will remain on the DATCP website with the ability for public comment for as long as the guidance document is in effect, pursuant to Wis. Stat. s. 227.112 (2).

State of Wisconsin

Veterinary Examining Board

2811 Agriculture Drive • PO Box 8911 • Madison, WI 53708-8911 • Wisconsin.gov

Guidance Document VEB-GD-001
Bull Semen Collection (Electro-Ejaculation)

Wis. Stat. § 89.03 (1)
Wis. Admin. Code § VE 7.02
10/23/19

Topic

This guidance document clarifies which procedures involving electro-ejaculation bull semen collection, as listed below, a licensed veterinarian must perform, which procedures may be delegated to a certified veterinary technician, and which procedures may be delegated to an unlicensed assistant.

1. Insert the probe
2. Ejaculate the bull
3. Collect the semen sample
4. Evaluate the semen for concentration, motility, and morphology
5. Measure scrotal circumference
6. Based on the evaluation parameters listed in 4 and 5, give a rating as to semen quality

Relevant Statutes and Administrative Code

Wis. Stat. § 89.02 (6) defines the practice of veterinary medicine as to examine into the fact or cause of animal health, disease or physical condition, or to treat, operate, prescribe or advise for the same, or to under-take, offer, advertise, announce, or hold out in any manner to do any of said acts, for compensation, direct or indirect, or in the expectation thereof.

Wis. Stat. § 89.03 (1) authorizes the board to promulgate rules to establish the scope of the practice permitted for veterinarians and veterinary technicians, within the limits of the definition under Wis. Stat. § 89.02 (6).

Wis. Admin. Code § VE 1.01 (5) defines “direct supervision” as immediate availability to continually coordinate, direct and inspect personally the practice of another.

Wis. Admin. Code § VE 7.02 (1) (a) limits the diagnosis and prognosis of animal diseases and conditions to veterinarians and prohibits the delegation of such acts to veterinary technicians or other persons not holding such license or permit.

Wis. Admin. Code § VE 7.02 (3) (b) allows veterinarians to delegate to certified veterinary technicians, while under the direct supervision of the veterinarian, the provision of observations and findings related to animal diseases and conditions to be utilized by a veterinarian in establishing a diagnosis or prognosis, including nonsurgical specimen collection.

Wis. Admin. Code § VE 7.02 (5) (a) allows veterinarians to delegate to unlicensed assistants, while under the direct supervision of the veterinarian, the provision of basic diagnostic studies, including nonsurgical specimen collection.

Wis. Admin. Code § VE 7.02 (6) (b) allows veterinarians to delegate to unlicensed assistants, while under the direct supervision of the veterinarian when the veterinarian is personally present on the premises where the services are provided, the provision of observations and findings related to animal diseases and conditions to be utilized by a veterinarian in establishing a diagnosis or prognosis.

Wis. Admin. Code § VE 7.02 (8) (c) requires that, when the veterinarian is not required to be personally present on the premises where the delegated services are performed, the veterinarian must be available at all times for consultation either in person or within 15 minutes of contact by telephone, by video conference, or by electronic communication device.

Board Position

The Board determined that steps 1 (insert the probe), 2 (ejaculate the bull), and 3 (collect the semen sample) are acts of nonsurgical specimen collection. As such, a veterinarian may delegate steps 1 through 3 to a certified veterinary technician under the direct supervision of the veterinarian (VE 7.02 (3) (b), Wis. Admin. Code) and/or to an unlicensed assistant under the direct supervision of the veterinarian (VE 7.02 (5) (a), Wis. Admin. Code).

The Board determined that step 4 (evaluate the semen for concentration, motility, and morphology) is within the scope of observations and findings related to animal diseases and conditions to be utilized by a veterinarian in establishing a diagnosis or prognosis. As such, a veterinarian may delegate step 4 to a certified veterinary technician under the direct supervision of the veterinarian (VE 7.02 (3) (b), Wis. Admin. Code) and/or to an unlicensed assistant under the direct supervision of the veterinarian while the veterinarian is personally present on the premises where the services are provided (VE 7.02 (6) (b), Wis. Admin Code).

The Board determined that step 5 (measure scrotal circumference) on its own would not be the practice of veterinary medicine. However, the process of bull semen collection is the practice of veterinary medicine. As such, all steps of the process of bull semen collection must either be performed by a veterinarian or be delegated by the veterinarian to a certified veterinary technician or an unlicensed assistant. A layperson could potentially measure scrotal circumference if the act is not a part of the process of bull semen collection and not a part of any other process that is the practice of veterinary medicine.

The Board determined that step 6 (based on the evaluation parameters listed in 4 and 5, give a rating as to semen quality) is a diagnosis. As such, step 6 is limited to veterinarians and may not be delegated to or performed by veterinary technicians or other persons not holding such a license or permit (VE 7.02 (1) (a), Wis. Admin. Code).

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	4/29/20
2) Requestor Name	Angela Fisher
3) Item Title for the Agenda	Guidance Document – Cannabis – Comments
4) Should the Item be in Open or Closed Session?	Open
5) Are there Attachments? (If yes, include file names)	Comment: "FW_ Proposed Guidance Document VEB-GD-002 Cannabis" Guidance Document: "VEB-GD-002 Cannabis" (The guidance document is also posted in the "Resources" section of OnBoard.)
6) Is a Public Appearance Anticipated?	No
7) Description of the Agenda Item	**This guidance document has been posted for the required comment period. No comments were received. At this meeting the guidance document will be considered for official adoption.** Wis. Stat. s. 227.112 (1) requires the Board to: - Post a proposed guidance document on the agency website (VEB-GD-002 was posted on 1/23/20) - Post a proposed guidance document in the Administrative Register with a comment period of at least 21 days (VEB-GD-002 was posted on 1/27/20) - Consider comments in determining whether to adopt the guidance document as originally proposed, modify the proposed guidance document, or take any other action. (Attached is a comment received on 2/26/20 for the Board's consideration.) Modifying and/or adopting the guidance document will require a motion by the Board. After adoption, the guidance document will remain on the DATCP website with the ability for public comment for as long as the guidance document is in effect, pursuant to Wis. Stat. s. 227.112 (2).

From: Kristine Collins <kristinecollins@saukpointvet.com>
Sent: Saturday, February 8, 2020 6:04 PM
To: DATCP Guidance Docs Comments <datcpguidancedocscomments@wisconsin.gov>
Subject: Proposed Guidance Document VEB-GD-002 Cannabis

To Whom it May Concern:

The way our profession deals with the ever increasing demand for products that include cannabis is going to be far reaching for a long time. We need to use caution yet keep an open mind for items that are generally considered safe or have shown to be effective in the management of animal maladies.

It is my hope that we come up with regulations regarding what may be considered safe including what parameters should be met or products on the market may be considered for recognition when discussing cannabis products.

It would be wise for us as a community to discuss why there are so many footprint stores allowed to sell cannabis products to humans, yet we are restricted (if that is the outcome) of discussing or finding a product that would be allowable for pets.

I, too, am concerned with the large scale and potentially unregulated market for cannabinoid products; yet, I do know several products that I have researched as safe, and even effective in particular cases.

It would be in the best interest of the veterinary community and for our clients and their pets for us to come to some agreement rather than trying to stifle conversation or product use for those pets that need it most.

To begin with, I have some concerns with the Guidance:

Page 2, 3rd paragraph:
Wis. Stat. SS89.068 (1) (a) prohibits making extra-label use of a drug on an animal without a prescription or in any manner not authorized by that prescription.

Hemp is labeled as a drug. This can be interpreted that this prohibits the use of hemp/CBD products if they are not being dispensed by the clinic. The point being that a prescription can only be made from a medicine that is commercially available and standardize or from a medicine that is known to the doctor and in the clinic. One would need to know the product and in order to make a prescription, it would assume it is also a recommendation (goes against VEBs position).

4th paragraph:
*Wis. Stat. SS89.068(1)(c)3. prohibits a veterinarian from prescribing a drug to a client for extra-label use on a patient unless **all** of the following apply:*

(a) A veterinary-client-patient relationship exists between the veterinarian, client and patient and the veterinarian has made a careful medical diagnosis of the condition of the patient within the context of that veterinary-client-patient relationship.
(b) The veterinarian determines that there is no drug that is marketed specifically to treat the patient's diagnosed condition, or determines that all the drugs that are marketed for that purpose are clinically ineffective.
(c) The veterinarian recommends procedures for the client to follow to ensure that the identity of the patient will be maintained.
(d) If the patient is a food-producing animal, the veterinarian prescribes a sufficient time period for the drug withdrawal before the food from the patient may be marketed.

Concerns:
(1)The concern with this portion is that they have defined "drug" as:
Drugs: Under the FD&C Act, any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure of the body of humans or animals, is a drug.

This could be used for anything that is a supplement intended to help with healing or therapeutic effect. This could include glucosamines, Omega 3 fatty acids, new vitamin formulation. I understand the intention but it could be prohibitive and overreaching.

1(a) "*Careful medical diagnosis*" - I understand the intention but there are times where we do not have a full diagnosis. The patient has pain in an area that is undetermined, or a GI disease that could be A, B or C. And the reason for not having the diagnosis may be the owner doesn't want to pursue. In that case, is this area still fulfilled?

1(b) "*no drug is marketed specifically to treat...or that all drugs that are marketed are ineffective*" - Does this mean we need to be sure every drug has been tried with the patient, even if the owner does not wish to try every drug? Or what if there is a cannabis drug and the owner cannot afford it and wishes to try a CBD or hemp product to begin with? What if we know that the hemp product or CBD product has been working? Does this risk our license?
1(c) ...*the Identity of the patient being maintained* - this needs to be better worded to indicate parameters in order for a veterinarian to meet ALL requirements.

Page 2-3 under the Federal Law and Regulation:

2018 Farm Bill removed hemp from the Controlled Substances.... and to date the FDA has not approved any cannabis Product for animal use.
...The Animal Medicinal Drug Use Clarification Act (AMDUCA) permits veterinarians to prescribe extra-label uses of FDA approved human and animal drugs for animals under certain conditions. Among other limitations, extra-label use of a drug is only allowed in circumstances when the health of an animal is threatened or suffering, or death may result.....

This indicates we can use medicines extra-label for FDA approved human drugs. Yet,the catch 22 here is: there are only a few FDA approved human CBD products or they are not readily available or affordable. If the idea (from Dr. Sharpless) is that unapproved drugs may put patients at risk, then by not allowing our voices to discuss options and recommendations with owners; then owner will instead go out on their own buying on-line or the local hemp store - so doesn't that put patients at risk? Wouldn't it be better that using our scientific mind to research products (and with the owners agreement that it is not FDA approved) and find products that may be the most beneficial and safe?

Under Foods (page 3 of 3)

> *Foods: All food ingredients must be approved by the FDA as either a food additive or as Generally Recognized as Safe (GRAS)...The FDA has approved three cannabis products as GRAS <u>for human use only</u>: hemp seed, hemp seed protein powder, and hemp seed oil.*

GRAS stands for Generally Recognized as Safe. I agree with this in general. This relates to the hemp plant (not distilled CBD). This paragraph indicates product contains hemp seed, help seed protein powder, and hemp seed oil are food. If we are allowing hemp oils (seeds), following the procedures for harvesting AND the product is known to be < 0.3% THC, and technically labeled as GRAS, then it should be allowed by definition. The fact that it may contain plant parts or leaves, as long as they have been tested as safe, it should be allowed GRAS by definition.; It is being labeled as a food under GRAS by definition.

Lastly -

The VEB's position is that cannabis products do not conform to FDA regulations. They state we may not administer, prescribe, dispense, refer or recommend such products.

This position goes against the idea that extra-label use of a drug is only allowed in circumstances when the health of an animal is threatened or suffering, or death may result. The use of supplements/drugs/hemp products should be allowed when an animal is suffering, or the death of that animal may result in the owner's choice to euthanize the pet due to not being able to use other means, or other means do not work. The law should allow all the veterinarians that wish to assist these owners in finding a hemp product or supplement as long as it contains 0.3% or less THC if that is the owner's wish. And to recommend products that have been identified as safe or effective for that patient WITHOUT worrying that the veterinarian's license is on the line.

Again, instead of the Veterinary Examining Board stifling the ability for us to discuss the differences in products, it may be more wise to investigate products that have been determined to be safe, and hopefully, effective.

For Example - Regarding products: *Standard Process* is a line of supplements that has rigorous testing standards regarding safety and is regulated for consistency. They also have a hemp product labeled for dogs that follows strict processing of hemp. This strict processing is done so they can use it in their human and dog products. This is a perfect example of a product that follows the food regulations of GRAS, and follows the guidelines for hemp production. It is tested to be safe for pets and humans and is

known to be <0.3% THC. I can attest to the effectiveness of this product in the treatment of pain in the few pets that this has been used with. It is likely there are others.

The point is rather than tie our hands and silence our scientific voice; it would be wiser for the Veterinary Examining Board or other Animal Entities to determine guidelines for allowable products to recommend in the vacuum of not having other FDA approved medications for pets.

--
Dr. Kristine Collins, DVM
Sauk Point Veterinary Clinic
608 829 0055
www.saukpointvet.com

State of Wisconsin

Veterinary Examining Board

2811 Agriculture Drive • PO Box 8911 • Madison, WI 53708-8911 • Wisconsin.gov

Guidance Document VEB-GD-002
Cannabis

Wis. Stat. § 89.03 (1)
Wis. Admin. Code § VE 7.06
1/22/20

Topic

This guidance document clarifies what a veterinarian may and may not do with regards to cannabis products.

Definitions

Cannabis is a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds. Federal law divides cannabis into two categories: hemp and marijuana.

Hemp is defined by the 7 USC 1639o(1) as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." The 2018 Farm Bill removed hemp from Schedule I of the Controlled Substances Act.

Marijuana/Marihuana is defined by 21 USC 802(16) as "all parts of the plant Cannabis sativa L., whether grown or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivate, mixture, or preparation of such plant, its seeds or resin," except for "hemp, as defined in section 1639o of title 7; or the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination." Marijuana/Marihuana is listed in Schedule I of the Controlled Substances Act.

THC is an abbreviation of delta-9-tetrahydrocannabinol, a compound of the cannabis plant. Hemp plants contain no more than 0.3 percent THC on a dry weight basis, and marijuana plants contain more than 0.3 percent THC on a dry weight basis.

CBD is an abbreviation of cannabidiol, a compound of the cannabis plant. Hemp plants and marijuana plants both contain CBD.

Hemp Seeds are the seeds of the Cannabis sativa plant. The seeds of the plant do not naturally contain THC or CBD. The seeds may pick up trace amounts of TCH and/or CBD during the harvesting and processing when they are in contact with other parts of the plant.

Relevant Statutes and Administrative Code

Wis. Stat. § 89.02 (6) defines the practice of veterinary medicine as to examine into the fact or cause of animal health, disease or physical condition, or to treat, operate, prescribe or advise for the same, or to under-take, offer, advertise, announce, or hold out in any manner to do any of said acts, for compensation, direct or indirect, or in the expectation thereof.

Wis. Stat. § 89.03 (1) authorizes the board to promulgate rules to establish the scope of the practice permitted for veterinarians and veterinary technicians, within the limits of the definition under Wis. Stat. § 89.02 (6).

Wis. Stat. § 89.068 (1) (a) prohibits making extra-label use of a drug on an animal without a prescription or in any manner not authorized by that prescription.

Wis. Stat. § 89.068 (1) (c) 3. prohibits a veterinarian from prescribing a drug to a client for extra-label use on a patient unless all of the following apply:

a. A veterinary-client-patient relationship exists between the veterinarian, client and patient and the veterinarian has made a careful medical diagnosis of the condition of the patient within the context of that veterinary-client-patient relationship.
b. The veterinarian determines that there is no drug that is marketed specifically to treat the patient's diagnosed condition, or determines that all of the drugs that are marketed for that purpose are clinically ineffective.
c. The veterinarian recommends procedures for the client to follow to ensure that the identity of the patient will be maintained.
d. If the patient is a food-producing animal, the veterinarian prescribes a sufficient time period for drug withdrawal before the food from the patient may be marketed.

Wis. Stat. § 89.07 (1) (b) classifies violating any federal or state statute or rule that substantially relates to the practice of veterinary medicine as unprofessional conduct that may result in disciplinary action by the Board.

Wis. Admin. Code § VE 7.06 (4) classifies violating or aiding and abetting the violation of any law or administrative rule or regulation substantially related to the practice of veterinary medicine as unprofessional conduct that may result in disciplinary action by the Board.

Federal Law and Regulation

The 2018 Farm Bill removed hemp from the Controlled Substance Act definition of marijuana. As a result, while marijuana remains a Schedule I drug, hemp is no longer a controlled substance under Federal law. The 2018 Farm Bill explicitly preserved the authority of the United States Food and Drug Administration (FDA) to regulate products containing cannabis or cannabis-derived compounds under the Food, Drug and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act. It is illegal to market or sell cannabis products in interstate commerce for animal use unless the FDA approves the product for animal use. To date, the FDA has not approved any cannabis product for animal use.

Drugs: Under the FD&C Act, any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure of the body of humans or animals, is a drug. To date, the FDA has not approved any cannabis-containing, cannabis-derived, or cannabis-related drugs for animal use. The FDA has approved one cannabis-derived (Epidiolex) and three cannabis-related (Marinol, Syndros, and Cesamet) prescription drugs for human use. The Animal Medicinal Drug Use Clarification Act (AMDUCA)

permits veterinarians to prescribe extra-label uses of FDA approved human and animal drugs for animals under certain conditions. Among other limitations, extra-label use of a drug is only allowed in circumstances when the health of an animal is threatened or suffering, or death may result from failure to treat.

Foods: All food ingredients must be approved by the FDA as either a food additive or as Generally Recognized as Safe (GRAS). The FDA also recognizes ingredients listed in the Official Publication of the Association of American Feed Control Officials (AAFCO). To date, neither the FDA nor AAFCO have approved any cannabis-containing or cannabis-derived foods for animal use. The FDA has approved three cannabis products as GRAS for human use only: hulled hemp seed, hemp seed protein powder, and hemp seed oil.

Supplements: The definition of dietary supplement only applies to human products. All products for animal use are classified as either foods or drugs and must be FDA approved. CBD and THC are the active ingredients in FDA approved human prescription drugs, so all products containing CBD or THC are classified as drugs.

See the attached FDA documents for additional information: "Remarks by Dr. Sharpless at the FDA Public Hearing on Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds," dated May 31, 2019; "FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers," dated November 13, 2019; and "FDA Warns 15 Companies for Illegally Selling Various Products Containing Cannabidiol as Agency Details Safety Concerns," dated November 25, 2019. See the FDA website at www.fda.gov for the latest information regarding FDA regulation of cannabis-containing and cannabis-derived products.

Board Position

Administering, prescribing, or dispensing drugs or food additives must conform to state and federal laws and regulations, including FDA regulations (Wis. Stat. § 89.07 (b) and Wis. Admin. Code § VE 7.06 (4)).

Referring or recommending drugs or food additives must conform to state and federal laws and regulations, including FDA regulations (Wis. Admin. Code § VE 7.06 (4)).

The Board acknowledges that cannabis products are currently being marketed to pet owners in a manner that does not conform to state and federal laws and regulations, including FDA regulations. To reduce the risk to animal health, veterinarians may discuss such products with their clients, provide available information, and express concerns. Veterinarians may also explain why they cannot administer, prescribe, dispense, refer, or recommend such products.

IN THIS SECTION

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SPEECH

Remarks by Dr. Sharpless at the FDA Public Hearing on Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds

MAY 31, 2019

Speech by

Norman E. "Ned" Sharpless, MD
Acting
Commissioner of Food and Drugs - Food and Drug Administration

White Oak, MD

(Remarks as prepared for delivery)

Thank you for joining FDA today for this public hearing titled “Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds”.

I am pleased to see that there is such interest in this topic. We have over 500 people registered to attend in person, over 800 people registered to join us remotely, and over 100 speakers on today’s agenda presenting on this topic.

We encourage all stakeholders – presenters, attendees, and those unable to participate in today’s hearing – to submit comments to our docket on this topic, which is open until July 2, 2019.

Docket comments will help inform FDA as we consider the important policy options related to the regulation of products containing cannabis or cannabis-derived compounds.

It is important to note that the FDA's role in the regulation of products containing cannabis or cannabis-derived compounds is not new.

Cannabis contains more than 80 biologically active chemical compounds, including the two best known compounds, delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).

If one of these compounds, or the plant itself, is added to a food or cosmetic, marketed as a drug, or otherwise added to an FDA-regulated product in interstate commerce, then it falls within FDA's jurisdiction. As I said, this is nothing new for FDA.

At the same time, some relevant laws have changed. First, some states have changed their laws to allow for "medical" use of marijuana or CBD, and others have begun allowing for recreational marijuana use, or decriminalized recreational marijuana possession.

Second, certain federal laws have changed as well. Parts of the Cannabis sativa plant have been controlled under the Federal Controlled Substances Act, or CSA, since 1970 under the drug class "Marihuana."

Marihuana is included in Schedule I of the CSA – the most restrictive schedule – due to its potential for abuse, largely attributable to the psychoactive effects of THC, and the absence of a currently accepted medical use in the United States.

Late last year, the federal scheduling of cannabis changed. The Agriculture Improvement Act of 2018, or the Farm Bill, removed hemp – meaning cannabis or derivatives of cannabis with a very low THC content (below 0.3% by dry weight) – from the CSA's definition of marijuana. As a result, while marijuana remains a Schedule I drug, hemp is no longer a controlled substance under Federal law.

As these laws have changed, FDA's authorities have become more relevant.

The 2018 Farm Bill explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds. In doing so, Congress recognized FDA's important public health role with respect to all the products it regulates – including when those products are or contain cannabis ingredients.

FDA treats substances derived from cannabis just like we do any other substances, and they are subject to the same authorities as any other substance.

Under FDA's authorities, the relevant legal requirements vary depending on which type of product we're talking about.

For example, if a product is being marketed as a drug – meaning, for example, that it's intended to have a therapeutic effect such as treating a disease or affecting the body's structure or function – then it's regulated as a drug, and it generally cannot be sold without FDA approval.

FDA has approved several drug products that contain compounds found in cannabis.

These include EPIDIOLEX, which contains CBD, for the treatment of specific types of seizures in certain pediatric patients, and MARINOL and SYNDROS, which contains dronabinol, a synthetic THC, for uses including the treatment of anorexia in patients with AIDS.

These drugs have important therapeutic value, and it is critical that we continue to do what we can to support the science needed to develop new drugs from cannabis.

Food, including dietary supplements, is regulated differently, but with the same overarching goal of protecting consumers.

We know that American consumers depend on FDA to help make sure that the food they eat, and that they serve to their families, is safe. We do this through a number of requirements.

For example, while we don't generally require foods to be approved by FDA before coming to market, we do require that a new food additive be approved as safe by FDA before being put in the food supply, unless the substance is generally recognized as safe, or GRAS.

This requirement applies to cannabis-derived ingredients, just as it does to any other substance. Americans deserve to know that substances being added to their foods are safe, regardless of the source.

I will note that several cannabis-derived substances have already come to market through the GRAS pathway.

In December, FDA announced that we completed our evaluation of GRAS notices for three hemp seed ingredients and had no objection to their being marketed in human foods for certain uses without approval, provided they comply with all other requirements.

As I mentioned earlier, however, some compounds found in cannabis – specifically, CBD and THC – have been studied and even approved as drugs. It's important to note that the Federal Food, Drug & Cosmetic Act prohibits adding drugs to human or animal food in interstate commerce.

That includes both substances that have been approved as drugs, as well as compounds for which substantial clinical investigations have been instituted. Similarly, the law excludes these products from the statutory definition of a dietary supplement.

Based on the information available to FDA, we have concluded that these provisions apply to CBD and THC. And while there is an exception when the substance was marketed as a food or dietary supplement before it was studied as a drug, we have concluded that that is not the case for CBD or THC.

What that means is that, under current law, CBD and THC cannot lawfully be added to a food or marketed as a dietary supplement.

Although the law says that FDA can issue regulations to create new exceptions to these statutory provisions, FDA has never issued a regulation like that for any substance.

So, if we were thinking about doing that for a substance like CBD, it would be new terrain for the FDA.

There are important reasons to generally prohibit putting drugs in the food supply. When FDA approves a drug, we carefully evaluate the risks and benefits of a specific formulation, dosage form, and strength for a particular population.

Often, we conclude that to be safely used, it requires a prescription or other medical supervision to help protect against potentially dangerous misuse.

THC and CBD are no exception.

There are real risks associated with both those substances and critical questions remain about the safety of their widespread use in foods and dietary supplements, as well as other consumer products – including cosmetics, which are subject to a separate regulatory framework.

And given the new interest in marketing cannabis products across the range of areas FDA regulates, we will need to carefully evaluate how all these pieces fit together in terms of how consumers might access cannabis products.

Nowhere is this truer than with CBD. While we have seen an explosion of interest in products containing CBD, there is still much that we don't know.

Prior to the 2018 Farm Bill, population-based research mostly included cannabis-focused observations in aggregate, rather than specific to CBD.

When hemp was removed as a controlled substance, this lack of research, and therefore evidence, to support CBD's broader use in FDA-regulated products, including in foods and dietary supplements, has resulted in unique complexities for its regulation, including many unanswered questions related to its safety.

For example, how much CBD is safe to consume in a day? What if someone applies a topical CBD lotion, consumes a CBD beverage or candy, and also consumes some CBD oil? How much is too much? How will it interact with other drugs the person might be taking? What if she's pregnant? What if children access CBD products like gummy edibles? What happens when someone chronically uses CBD for prolonged periods?

These and many other questions represent important and significant gaps in our knowledge.

To help us evaluate these questions, as well as potential pathways for CBD products, FDA has formed an internal working group to address these data gaps specifically. You'll be hearing more from this group in the months to come.

FDA is aware that some companies appear to be marketing products containing cannabis and cannabis-derived compounds in ways that violate the law.

FDA has issued warning letters to companies selling unapproved CBD products.

Our biggest concern is the marketing of products that put the health and safety of consumers at risk, such as those claiming to prevent, diagnose, mitigate, treat, or cure serious diseases, such as cancer, in the absence of requisite approvals.

Selling unapproved drug products with unsubstantiated therapeutic claims is a violation of the law, and puts patients at risk.

Patients and other consumers may be influenced not to use approved therapies to treat serious and even fatal diseases.

That being said, the agency does not have a policy of enforcement discretion with respect to any CBD products.

There are lots of questions we will need to answer to ensure that FDA is taking an appropriate, well-informed, and science-based approach to the regulation of cannabis and cannabis derivatives, including CBD.

We hope that this meeting, and the comments submitted to our public docket, will help us as we try to approach this issue in an informed way. This hearing is an important step in our continued evaluation of cannabis and cannabis-derived compounds in FDA-regulated products.

I thank you all for taking the time to join us today and your contributions toward this important topic. We have a full agenda....

More Speeches by
FDA Officials (/news-events/speeches-fda-officials)

FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)

On this page:

There is a significant interest in the development of therapies and other consumer products derived from cannabis and its components, including cannabidiol (CBD). FDA recognizes the potential opportunities that cannabis or cannabis-derived compounds may offer and acknowledges the significant interest in these possibilities. However, FDA is aware that some companies are marketing products containing cannabis and cannabis-derived compounds in ways that violate the Federal Food, Drug and Cosmetic Act (FD&C Act) and that may put the health and safety of consumers at risk. The agency is committed to protecting the public health while also taking steps to improve the efficiency of regulatory pathways for the lawful marketing of appropriate cannabis and cannabis-derived products. FDA has a number of resources available that address cannabis and cannabis-derived products, such as CBD, and the agency wants to ensure that consumers and other stakeholders have access to these resources in a centralized location.

Consumer Information

- What You Should Know About Using Cannabis, Including CBD, When Pregnant or Breastfeeding (/consumers/consumer-updates/what-you-should-know-about-using-cannabis-including-cbd-when-pregnant-or-breastfeeding)
- What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD (/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis)

FDA Communications

- Remarks at the Council for Responsible Nutrition Conference (/news-events/speeches-fda-officials/remarks-lowell-schiller-jd-council-responsible-nutrition-conference-1172019-11072019)
- Remarks at the National Industrial Hemp Council 2019 Hemp Business Summit (/news-events/speeches-fda-officials/remarks-national-industrial-hemp-council-2019-hemp-business-summit-08132019)
- Congressional Testimony: Hemp Production and the 2018 Farm Bill (/news-events/congressional-testimony/hemp-production-and-2018-farm-bill-07252019)
    - Archived Video (https://www.agriculture.senate.gov/hearings/hemp-production-and-the-2018-farm-bill)
- FDA is Committed to Sound, Science-based Policy on CBD (/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd)
- Statement on new steps to advance agency's continued evaluation of potential regulatory pathways for cannabis-containing and cannabis-derived products (/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-advance-agencys-continued-evaluation)

Regulatory Resources

- Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing
    - Federal Register Notice (https://www.federalregister.gov/documents/2019/04/03/2019-06436/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds)
    - Public Hearing Page (/news-events/fda-meetings-conferences-and-workshops/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds)
    - Public Docket (https://www.regulations.gov/docket?D=FDA-2019-N-1482)

- Warning Letters and Test Results for Cannabidiol-Related Products (/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products)
- State, Local, Tribal, Territorial (SLTT) Regulatory Officials: FDA is committed to working with our SLTT public health regulatory partners as developments occur in the regulatory landscape. Please contact the Intergovernmental Affairs team with any questions at IGA@fda.hhs.gov (mailto:IGA@fda.hhs.gov).

Questions and Answers

Below are a number of frequently asked questions and answers on this topic.

1. What are cannabis and marijuana?
2. How does the 2018 Farm Bill define hemp? What does it mean for FDA-regulated products?
3. Has FDA approved any medical products containing cannabis or cannabis-derived compounds such as CBD?
4. Aside from Epidiolex, are there other CBD drug products that are FDA-approved? What about the products I've seen in stores or online?
5. Why hasn't FDA approved more products containing cannabis or cannabis-derived compounds for medical uses?
6. What is FDA's reaction to states that are allowing cannabis to be sold for medical uses without the FDA's approval?
7. Has the agency received any adverse event reports associated with cannabis use for medical conditions?
8. Is it legal for me to sell CBD products?
9. Can THC or CBD products be sold as dietary supplements?
10. Is it legal, in interstate commerce, to sell a food (including any animal food or feed) to which THC or CBD has been added?
11. In making the two previous determinations about THC, why did FDA conclude that THC is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act? In making the two previous determinations about CBD, why did FDA determine that substantial clinical investigations have been authorized for and/or instituted, and that the existence of such investigations has been made public?

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1. What are cannabis and marijuana?

A. Cannabis is a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds. The most commonly known compounds are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). Parts of the *Cannabis sativa* plant have been controlled under the Controlled Substances Act (CSA) since 1970 under the drug class "Marihuana" (commonly referred to as "marijuana") [21

U.S.C. 802(16)]. "Marihuana" is listed in Schedule I of the CSA due to its high potential for abuse, which is attributable in large part to the psychoactive effects of THC, and the absence of a currently accepted medical use of the plant in the United States.

2. How does the 2018 Farm Bill define hemp? What does it mean for FDA-regulated products?

A. At the federal level, the Agriculture Improvement Act of 2018, Pub. L. 115-334, (the 2018 Farm Bill) was signed into law on Dec. 20, 2018. Among other things, this new law changes certain federal authorities relating to the production and marketing of hemp, defined as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." These changes include removing hemp from the CSA, which means that cannabis plants and derivatives that contain no more than 0.3 percent THC on a dry weight basis are no longer controlled substances under federal law.

The 2018 Farm Bill, however, explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the FD&C Act and section 351 of the Public Health Service Act (PHS Act). FDA treats products containing cannabis or cannabis-derived compounds as it does any other FDA-regulated products — meaning they're subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of whether the cannabis or cannabis-derived compounds are classified as hemp under the 2018 Farm Bill.

3. Has FDA approved any medical products containing cannabis or cannabis-derived compounds such as CBD?

A. To date, the agency has not approved a marketing application for cannabis for the treatment of any disease or condition. FDA has, however, approved one cannabis-derived and three cannabis-related drug products. These approved products are only available with a prescription from a licensed healthcare provider.

FDA has approved Epidiolex (/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms), which contains a purified form of the drug substance CBD for the treatment of seizures

associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. That means FDA has concluded that this particular drug product is safe and effective for its intended use.

The agency also has approved Marinol and Syndros for therapeutic uses in the United States, including for the treatment of anorexia associated with weight loss in AIDS patients. Marinol and Syndros include the active ingredient dronabinol, a synthetic delta-9- tetrahydrocannabinol (THC) which is considered the psychoactive component of cannabis. Another FDA-approved drug, Cesamet, contains the active ingredient nabilone, which has a chemical structure similar to THC and is synthetically derived.

4. Aside from Epidiolex, are there other CBD drug products that are FDA-approved? What about the products I've seen in stores or online?

A. No. There are no other FDA-approved drug products that contain CBD. We are aware that some firms are marketing CBD products to treat diseases or for other therapeutic uses , and we have issued several warning letters (/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products) to such firms. Under the FD&C Act, any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug. Drugs must generally either receive premarket approval by FDA through the New Drug Application (NDA) process or conform to a "monograph" for a particular drug category, as established by FDA's Over-the-Counter (OTC) Drug Review. CBD was not an ingredient considered under the OTC drug review. An unapproved new drug cannot be distributed or sold in interstate commerce.

FDA continues to be concerned at the proliferation of products asserting to contain CBD that are marketed for therapeutic or medical uses although they have not been approved by FDA. Often such products are sold online and are therefore available throughout the country. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments also raises significant public health concerns, because patients and other consumers may be influenced not to use approved therapies to treat serious and even fatal diseases.

Unlike drugs approved by FDA, products that have not been subject to FDA review as part of the drug approval process have not been evaluated as to whether they work, what the proper dosage may be if they do work, how they could interact with other drugs, or whether they have dangerous side effects or other safety concerns.

The agency has and will continue to monitor the marketplace and take action as needed to protect the public health against companies illegally selling cannabis and cannabis-derived products that can put consumers at risk and that are being marketed for therapeutic uses for which they are not approved. At the same time, FDA recognizes the potential therapeutic opportunities that cannabis or cannabis-derived compounds could offer and acknowledges the significant interest in these possibilities. FDA continues to believe that the drug approval process represents the best way to help ensure that safe and effective new medicines, including any drugs derived from cannabis, are available to patients in need of appropriate medical therapy. The Center for Drug Evaluation and Research (CDER) is committed to supporting the development of new drugs, including cannabis and cannabis-derived drugs, through the investigational new drug (IND) and drug approval process (see Question #16).

5. Why hasn't FDA approved more products containing cannabis or cannabis-derived compounds for medical uses?

A. FDA is aware that unapproved cannabis or cannabis-derived products are being used for the treatment of a number of medical conditions including, for example, AIDS wasting, epilepsy, neuropathic pain, spasticity associated with multiple sclerosis, and cancer and chemotherapy-induced nausea.

To date, FDA has not approved a marketing application for cannabis for the treatment of any disease or condition and thus has not determined that cannabis is safe and effective for any particular disease or condition. The agency has, however, approved one cannabis-derived and three cannabis-related drug products (see Question #2).

FDA relies on applicants and scientific investigators to conduct research. The agency's role, as laid out in the FD&C Act, is to review data submitted to the FDA in an application for approval to ensure that the drug product meets the statutory standards for approval.

The study of cannabis and cannabis-derived compounds in clinical trial settings is needed to assess the safety and effectiveness of these substances for the treatment of any disease or condition. FDA's December 2016 *Guidance for Industry: Botanical Drug Development* (/regulatory-information/search-fda-guidance-

documents/botanical-drug-development-guidance-industry) provides specific recommendations on submitting INDs for botanical drug products, such as those derived from cannabis, in support of future marketing applications for these products. The FDA will continue to facilitate the work of companies interested in appropriately bringing safe, effective, and quality products to market, including scientifically-based research concerning the medicinal uses of cannabis. Additional information concerning research on the medical use of cannabis is available from the National Institutes of Health, particularly the National Cancer Institute (https://www.cancer.gov/) (NCI) and National Institute on Drug Abuse (https://www.drugabuse.gov/drugs-abuse/marijuana/nih-research-marijuana-cannabinoids) (NIDA).

6. What is FDA's reaction to states that are allowing cannabis to be sold for medical uses without the FDA's approval?

A. The FDA is aware that several states have either passed laws that remove state restrictions on the medical use of cannabis and its derivatives or are considering doing so. It is important to conduct medical research into the safety and effectiveness of cannabis products through adequate and well-controlled clinical trials. We welcome the opportunity to talk with states who are considering support for medical research of cannabis and its derivatives, so that we can provide information on Federal and scientific standards.

7. Has the agency received any adverse event reports associated with cannabis use for medical conditions?

A. The agency has received reports of adverse events in patients using cannabis or cannabis-derived products to treat medical conditions. The FDA reviews such reports and will continue to monitor adverse event reports for any safety signals, with a focus on serious adverse effects.

Information from adverse event reports regarding cannabis use is extremely limited; FDA primarily receives adverse event reports for approved products. General information on the potential adverse effects of using cannabis and its constituents can come from clinical trials that have been published, as well as from spontaneously reported adverse events sent to the FDA. Additional information about the safety and effectiveness of cannabis and its constituents is needed. Clinical trials of cannabis conducted under an IND application could collect this important information as a part of the drug development process.

8. Is it legal for me to sell CBD products?

A. It depends, among other things, on the intended use of the product and how it is labeled and marketed. Even if a CBD product meets the definition of "hemp" under the 2018 Farm Bill (see Question #2), it still must comply with all other applicable laws, including the FD&C Act. The below questions and answers explain some of the ways that specific parts of the FD&C Act can affect the legality of CBD products.

We are aware that state and local authorities are fielding numerous questions about the legality of CBD. There is ongoing communication with state and local officials to answer questions about requirements under the FD&C Act, to better understand the landscape at the state level, and to otherwise engage with state/local regulatory partners.

9. Can THC or CBD products be sold as dietary supplements?

A. No. Based on available evidence, FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)]. Under that provision, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are excluded from the definition of a dietary supplement. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations (21 CFR 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.

There is an exception to section 201(ff)(3)(B) if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable. However, based on available evidence, FDA has concluded that this is not the case for THC or CBD.

FDA is not aware of any evidence that would call into question its current conclusions that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act. Interested parties may present the

agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not caused us to change our conclusions.

When a substance is excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act, the exclusion applies unless FDA, in the agency's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under the FD&C Act. To date, no such regulation has been issued for any substance.

Ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of this exclusion, and therefore might be able to be marketed as dietary supplements. However, all products marketed as dietary supplements must comply with all applicable laws and regulations governing dietary supplement products. For example, manufacturers and distributors who wish to market dietary supplements that contain "new dietary ingredients" (i.e., dietary ingredients that were not marketed in the United States in a dietary supplement before October 15, 1994) generally must notify FDA about these ingredients (see section 413 (d) of the FD&C Act [21 U.S.C. § 350b(d)]). Generally, the notification must include information demonstrating that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling. A dietary supplement is adulterated if it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that the ingredient does not present a significant or unreasonable risk of illness or injury (see section 402(f)(1)(B) of the FD&C Act [21 U.S.C. 342(f)(1)(B)]).

Numerous other legal requirements apply to dietary supplement products, including requirements relating to Current Good Manufacturing Practices (CGMPs) (/food/current-good-manufacturing-practices-cgmps/current-good-manufacturing-practices-cgmps-dietary-supplements) and labeling. Information about these requirements, and about FDA requirements across all product areas, can be found on FDA's website.

10. Is it legal, in interstate commerce, to sell a food (including any animal food or feed) to which THC or CBD has been added?

A. No. Under section 301(ll) of the FD&C Act [21 U.S.C. § 331(ll)], it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. There are exceptions, including when the drug was marketed in food before the drug was approved or before the substantial clinical investigations involving the drug had been instituted or, in the case of animal feed, that the drug is a new animal drug approved for use in feed and used according to the approved labeling. However, based on available evidence, FDA has concluded that none of these is the case for THC or CBD. FDA has therefore concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which THC or CBD has been added. FDA is not aware of any evidence that would call into question these conclusions. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not caused us to change our conclusions.

When this statutory prohibition applies to a substance, it prohibits the introduction into interstate commerce of any food to which the substance has been added unless FDA, in the agency's discretion, has issued a regulation approving the use of the substance in the food (section 301(ll)(2) of the FD&C Act [21 U.S.C. § 331(ll)(2)]). To date, no such regulation has been issued for any substance.

Ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of 301(ll), and therefore might be able to be added to food. For example, as discussed in Question #12, certain hemp seed ingredients can be legally marketed in human food. However, all food ingredients must comply with all applicable laws and regulations. For example, by statute, any substance intentionally added to food is a food additive, and therefore subject to premarket review and approval by FDA, unless the substance is generally recognized as safe (GRAS) by qualified experts under the conditions of its intended use, or the use of the substance is otherwise excepted from the definition of a food additive (sections 201(s) and 409 of the FD&C Act [21 U.S.C. §§ 321(s) and 348]). Aside from the three hemp seed ingredients mentioned in Question #12, no other cannabis or cannabis-derived ingredients have been the subject of a food additive petition, an evaluated GRAS notification, or have otherwise been approved for use in food by FDA. Food

companies that wish to use cannabis or cannabis-derived ingredients in their foods are subject to the relevant laws and regulations that govern all food products, including those that relate to the food additive and GRAS processes.

11. In making the two previous determinations about THC, why did FDA conclude that THC is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act? In making the two previous determinations about CBD, why did FDA determine that substantial clinical investigations have been authorized for and/or instituted, and that the existence of such investigations has been made public?

A. THC (dronabinol) is the active ingredient in the approved drug products, Marinol capsules (and generics) and Syndros oral solution. CBD is the active ingredient in the approved drug product, Epidiolex.

The existence of substantial clinical investigations regarding THC and CBD have been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex. (See Sativex Commences US Phase II/III Clinical Trial in Cancer Pain (https://www.gwpharm.com/about/news/sativexr-commences-us-phase-iiiii-clinical-trial-cancer-pain) (http://www.fda.gov/about-fda/website-policies/website-disclaimer))

12. Can hulled hemp seed, hemp seed protein powder, and hemp seed oil be used in human food?

A. In December 2018, FDA completed its evaluation (/food/cfsan-constituent-updates/fda-responds-three-gras-notices-hemp-seed-derived-ingredients-use-human-food) of three generally recognized as safe (GRAS) notices for the following hemp seed-derived food ingredients: hulled hemp seed, hemp seed protein powder, and hemp seed oil. FDA had no questions regarding the company's conclusion that the use of such products as described in the notices is safe. Therefore, these products can be legally marketed in human foods for the uses described in the notices, provided they comply with all other requirements. These GRAS notices related only to the use of these ingredients in human food. To date, FDA has not received any GRAS notices for the use of hemp-derived ingredients in animal food (see Question #25).

Hemp seeds are the seeds of the *Cannabis sativa* plant. The seeds of the plant do not naturally contain THC or CBD. The hemp seed-derived ingredients that are the subject of these GRAS notices contain only trace amounts of THC and CBD, which the seeds

may pick up during harvesting and processing when they are in contact with other parts of the plant. Consumption of these hemp seed-derived ingredients is not capable of making consumers "high."

The GRAS conclusions can apply to ingredients for human food marketed by other companies, if they are manufactured in a way that is consistent with the notices and they meet the listed specifications. Some of the intended uses for these ingredients include adding them as source of protein, carbohydrates, oil, and other nutrients to beverages (juices, smoothies, protein drinks, plant-based alternatives to dairy products), soups, dips, spreads, sauces, dressings, plant-based alternatives to meat products, desserts, baked goods, cereals, snacks and nutrition bars. Products that contain any of these hemp seed-derived ingredients must declare them by name on the ingredient list.

These GRAS conclusions do not affect the FDA's position on the addition of CBD and THC to food.

13. What is FDA's position on cannabis and cannabis-derived ingredients in cosmetics?

A. A cosmetic is defined in 201(i) as "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap."

Under the FD&C Act, cosmetic products and ingredients are not subject to premarket approval by FDA, except for most color additives. Certain cosmetic ingredients are prohibited or restricted by regulation, but currently that is not the case for any cannabis or cannabis-derived ingredients. Ingredients not specifically addressed by regulation must nonetheless comply with all applicable requirements, and no ingredient – including a cannabis or cannabis-derived ingredient – can be used in a cosmetic if it causes the product to be adulterated or misbranded in any way. A cosmetic generally is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual (section 601(a) of the FD&C Act [21 U.S.C. § 361(a)]).

If a product is intended to affect the structure or function of the body, or to diagnose, cure, mitigate, treat or prevent disease, it is a drug, or possibly both a cosmetic and a drug, even if it affects the appearance. (See Question #3 for more information about drugs.)

FDA can take action if it has information that an ingredient or cosmetic product is unsafe to consumers. Consumers can report adverse events associated with cosmetic products via the FDA's MedWatch reporting system, either online or by phone at 1-800-FDA-1088, or by contacting your nearest FDA district office consumer complaint coordinator. For more information, please see the FDA's webpage on how to report a cosmetic-related complaint (/cosmetics/cosmetics-compliance-enforcement/how-report-cosmetic-related-complaint).

14. Will FDA take action against cannabis or cannabis-related products that are in violation of the FD&C Act?

A. The FDA has sent warning letters (/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products) in the past to companies illegally selling CBD products that claimed to prevent, diagnose, treat, or cure serious diseases, such as cancer. Some of these products were in further violation of the FD&C Act because they were marketed as dietary supplements or because they involved the addition of CBD to food.

When a product is in violation of the FD&C Act, FDA considers many factors in deciding whether or not to initiate an enforcement action. Those factors include, among other things, agency resources and the threat to the public health. FDA also may consult with its federal and state partners in making decisions about whether to initiate a federal enforcement action.

15. Can I import or export cannabis-containing or cannabis-derived products?

A. General information about the import/export of drug products regulated by FDA (/drugs/guidance-compliance-regulatory-information/import-export-compliance-branch-iecb) can be found online here. The Drug Enforcement Administration (https://www.dea.gov/) (DEA) is the federal agency responsible for enforcing the controlled substance laws and regulations in the U.S. and, as such, should be consulted with respect to any regulations/requirements they may have regarding the

import or export of products containing cannabis. Please see here for information about importing or exporting food ingredients (/food/guidance-regulation-food-and-dietary-supplements/food-imports-exports).

Regarding imports, if it appears that an article is adulterated, misbranded, in violation of section 505 of the FD&C Act, or prohibited from introduction or delivery for introduction into interstate commerce under section 301(ll) of the FD&C Act, such article will be refused admission (see section 801(a)(3) of the FD&C Act [21 U.S.C. § 381(a)(3)]).

Research and Expanded Access

16. What is FDA's role when it comes to the investigation of cannabis and cannabis-derived products for medical use?

A. To conduct clinical research that can lead to an approved new drug, including research using materials from plants such as cannabis, researchers need to work with the FDA and submit an IND application to the Center for Drug Evaluation and Research (CDER). The IND application process gives researchers a path to follow that includes regular interactions with the FDA to support efficient drug development while protecting the patients who are enrolled in the trials. For research for use as an animal drug product, researchers would establish an investigational new animal drug (INAD) file with the Center for Veterinary Medicine to conduct their research, rather than an IND with CDER.

As discussed above (see Question #2), the 2018 Farm Bill removed hemp from the CSA. This change may streamline the process for researchers to study cannabis and its derivatives, including CBD, that fall under the definition of hemp, which could speed the development of new drugs.

Conducting clinical research using cannabis-related substances that are scheduled by the DEA often involves interactions with several federal agencies. This includes: a registration administered by the DEA; obtaining the cannabis for research from NIDA, within the National Institutes of Health, or another DEA-registered source; and review by the FDA of the IND or INAD application and research protocol. Additionally:

- For a Schedule I controlled substance under the CSA, DEA provides researchers with investigator and protocol registrations and has Schedule I-level security requirements at the site cannabis will be studied.

- NIDA provides research-grade cannabis for scientific study. The agency is responsible for overseeing the cultivation of cannabis for medical research and has contracted with the University of Mississippi to grow cannabis for research at a secure facility. Cannabis of varying potencies and compositions is available. DEA also may allow additional growers (https://www.federalregister.gov/documents/2016/08/12/2016-17955/applications-to-become-registered-under-the-controlled-substances-act-to-manufacture-marijuana-to) to register with the DEA to produce and distribute cannabis for research purposes.
- Researchers work with the FDA and submit an IND application to the appropriate division in the Office of New Drugs in CDER depending on the therapeutic indication. Based on the results obtained in studies conducted at the IND stage, sponsors may submit a marketing application for formal approval of the drug.

17. Does the FDA object to the clinical investigation of cannabis for medical use?

A. No. The FDA believes that scientifically valid research conducted under an IND application is the best way to determine what patients could benefit from the use of drugs derived from cannabis. The FDA supports the conduct of that research by:

1. Providing information on the process needed to conduct clinical research using cannabis.
2. Providing information on the specific requirements needed to develop a drug that is derived from a plant such as cannabis. In December 2016, the FDA updated its Guidance for Industry: Botanical Drug Development (/regulatory-information/search-fda-guidance-documents/botanical-drug-development-guidance-industry), which provides sponsors with guidance on submitting IND applications for botanical drug products.
3. Providing specific support for investigators interested in conducting clinical research using cannabis and its constituents as a part of the IND process through meetings and regular interactions throughout the drug development process.
4. Providing general support to investigators to help them understand and follow the procedures to conduct clinical research through the FDA Center for Drug Evaluation and Research's Small Business and Industry Assistance group

(/drugs/development-approval-process-drugs/cder-small-business-industry-assistance-sbia).

18. How can patients gain access to cannabis or cannabis-derived products for medical use through expanded access?

A. Expanded access (/news-events/public-health-focus/expanded-access) is a potential pathway for a patient with a serious or life-threatening disease or condition to try an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when there are no comparable or satisfactory therapies available. Manufacturers may be able to make investigational drugs available to individual patients in certain circumstances through expanded access, as described in the FD&C Act and implementing regulations.

19. Can patients gain access to cannabis or cannabis-derived products for medical use through Right to Try?

A. Information for patients on Right to Try (/patients/learn-about-expanded-access-and-other-treatment-options/right-try) (RTT) is available on our website. RTT is designed to facilitate access to certain investigational drugs through direct interactions between patients, their physicians and drug sponsors – FDA is not involved in these decisions. Sponsors developing drugs for life-threatening conditions are responsible for determining whether to make their products available to patients who qualify for access under RTT. If you are interested in RTT, you should discuss this pathway with your licensed physician. Companies who develop drugs and biologics, also known as sponsors, can provide information about whether their drug/biologic is considered an eligible investigational drug under RTT and if they are able to provide the drug/biologic under the RTT Act.

Children and Pregnant/Lactating Women

20. Does the FDA have concerns about administering a cannabis product to children?

A. We understand that parents are trying to find treatments for their children's medical conditions. However, the use of untested drugs can have unpredictable and unintended consequences. Caregivers and patients can be confident that FDA-approved drugs have been carefully evaluated for safety, efficacy, and quality, and are monitored by the FDA once they are on the market. The FDA continues to support sound, scientifically-based research into the medicinal uses of drug products

containing cannabis or cannabis-derived compounds, and will continue to work with companies interested in bringing safe, effective, and quality products to market. With the exception of Epidiolex, Marinol, and Syndros, no product containing cannabis or cannabis-derived compounds (either plant-based or synthetic) has been approved as safe and effective for use in any patient population, whether pediatric or adult.

21. Does the FDA have concerns about administering a cannabis product to pregnant and lactating women?

A. The FDA is aware that there are potential adverse health effects with use of cannabis products containing THC in pregnant or lactating women. Published scientific literature reports potential adverse effects of cannabis use in pregnant women, including fetal growth restriction, low birth weight, preterm birth, small-for-gestational age, neonatal intensive care unit (NICU) admission, and stillbirth. [1, 2, 3] Based on published animal research, there are also concerns that use of cannabis during pregnancy may negatively impact fetal brain development. [4, 5, 6] The American College of Obstetricians and Gynecologists (ACOG) recommends that women who are pregnant or contemplating pregnancy should be encouraged to discontinue cannabis use. In addition, ACOG notes that there are insufficient data to evaluate the effects of cannabis use on breastfed infants; therefore, cannabis use is discouraged when breastfeeding. [7] Pregnant and lactating women should talk with a health care provider about the potential adverse health effects of cannabis use.

22. What does the FDA think about making CBD available to children with epilepsy?

A. The FDA has approved Epidiolex, which contains a purified form of the drug substance CBD, for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. That means the FDA has concluded that this particular drug product is safe and effective for its intended use. Controlled clinical trials testing the safety and efficacy of a drug, along with careful review through the FDA's drug approval process, is the most appropriate way to bring cannabis-derived treatments to patients. Because of the adequate and well-controlled clinical studies that supported this approval, and the assurance of manufacturing quality standards, prescribers can have confidence in the drug's uniform strength and consistent delivery that support appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes.

23. What should I do if my child eats something containing cannabis?

A. With the exception of products such as the hemp seed ingredients discussed in Question #12, which have been evaluated for safety, it is important to protect children from accidental ingestion of cannabis and cannabis-containing products. FDA recommends that these products are kept out of reach of children to reduce the risk of accidental ingestion. If the parent or caregiver has a reasonable suspicion that the child accidentally ingested products containing cannabis, the child should be taken to a physician or emergency department, especially if the child acts in an unusual way or is/feels sick.

Pets and other Animals

24. I've seen cannabis products being marketed for pets. Are they safe?

A. FDA is aware of some cannabis products being marketed as animal health products. We want to stress that FDA has not approved cannabis for any use in animals, and the agency cannot ensure the safety or effectiveness of these products. For these reasons, FDA cautions pet-owners against the use of such products and recommends that you talk with your veterinarian about appropriate treatment options for your pet.

Signs that your pet may be suffering adverse effects from ingesting cannabis may include lethargy, depression, heavy drooling, vomiting, agitation, tremors, and convulsions.

If you have concerns that your pet is suffering adverse effects from ingesting cannabis or any substance containing cannabis, consult your veterinarian, local animal emergency hospital or an animal poison control center immediately.

While the agency is aware of reports of pets consuming various forms of cannabis, to date, FDA has not directly received any reports of adverse events associated with animals given cannabis products. However, adverse events from accidental ingestion are well-documented in scientific literature. If you feel your animal has suffered from ingesting cannabis, we encourage you to report the adverse event to the FDA. Please visit Reporting Information about Animal Drugs and Devices (/animal-veterinary/report-problem/how-report-animal-drug-side-effects-and-product-problems) to learn more about how to report an adverse event related to an animal drug or for how to report an adverse event or problem with a pet food.

25. Can hemp be added to animal food?

A. All ingredients in animal food must be the subject of an approved food additive petition or generally recognized as safe (GRAS) for their intended use in the intended species. If an animal food contains an ingredient that is not the subject of an approved food additive petition or GRAS for its intended use in the intended species, that animal food would be adulterated under section 402(a)(2)(C)(i) of the FD&C Act [21 U.S.C. § 342(a)(2)(C)(i)]. In coordination with state feed control officials, CVM also recognizes ingredients listed in the Official Publication (OP) of the Association of American Feed Control Officials (AAFCO) as being acceptable for use in animal food. At this time, there are no approved food additive petitions or ingredient definitions listed in the AAFCO OP for any substances derived from hemp, and we are unaware of any GRAS conclusions regarding the use of any substances derived from hemp in animal food. Learn more about animal food ingredient submissions (/animal-veterinary/safety-health/safe-feed) here.

With respect to products labeled to contain "hemp" that may also contain THC or CBD, as mentioned above it is a prohibited act under section 301(ll) of the FD&C Act to introduce or deliver for introduction into interstate commerce any animal food to which THC or CBD has been added.

26. Can approved human drugs containing CBD or synthetic THC be used extralabel in animals?

A. The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), permits veterinarians to prescribe extralabel uses of approved human and animal drugs for animals under certain conditions. Extralabel use must comply with all the provisions of AMDUCA and its implementing regulation at 21 CFR § 530. Among other limitations, these provisions allow extralabel use of a drug only on the lawful order of a licensed veterinarian in the context of a valid veterinarian-client-patient relationship and only in circumstances when the health of an animal is threatened or suffering, or death may result from failure to treat.

In addition, under 21 CFR 530.20, extralabel use of an approved human drug in a food-producing animal is not permitted if an animal drug approved for use in food-producing animals can be used in an extralabel manner for the use. In addition, under 21 CFR 530.20(b)(2), if scientific information on the human food safety aspect of the use of the approved human drug in food-producing animals is not available, the veterinarian must take appropriate measures to ensure that the animal and its food products will not enter the human food supply.

For more information on extralabel use of FDA approved drugs in animals, see Extralabel Use of FDA Approved Drugs In Animals (/animal-veterinary/acts-rules-regulations/animal-medicinal-drug-use-clarification-act-1994-amduca).

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[1] Gray, et al. Identifying Prenatal Cannabis Exposure and Effects of Concurrent Tobacco Exposure on Neonatal Growth. Clinical Chemistry. 2010; 56(9): 1442-1450.

[2] Gunn, et al. Prenatal Exposure to cannabis and maternal and child health outcomes: a systematic review and meta-analysis. BMJ Open. 2016; 6:e009986.

[3] Hayatbakhsh, et al. Birth Outcomes associated with cannabis use before and during pregnancy. Pediatric Research. 2012; 71 (2): 215-219.

[4] Silva, et al. Prenatal tetrahydrocannabinol (THC) alters cognitive function and amphetamine response from weaning to adulthood in the rat. Neurotoxicol and Teratol 2012; 34(1): 63-71.

[5] Trezza, et al. Effects of perinatal exposure to delta-9-tetrahydrocannabinol on the emotional reactivity of the offspring: a longitudinal behavioral study in Wistar rats. Psychopharmacology (Berl) 2008; 198(4): 529-537.

[6] Campolongo, et al. Perinatal exposure to delta-9-tetrahydrocannabinol causes enduring cognitive deficits associated with alteration of cortical gene expression and neurotransmission in rats. Addict Biol 2007; 12(3-4): 485–495.

[7] ACOG Committee Opinion: Marijuana Use During Pregnancy and Lactation (https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Marijuana-Use-During-Pregnancy-and-Lactation) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

FDA NEWS RELEASE

FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns

Violations include marketing unapproved new human and animal drugs, selling CBD products as dietary supplements, and adding CBD to human, animal foods

For Immediate Release:

November 25, 2019

Today, the U.S. Food and Drug Administration issued warning letters to 15 companies for illegally selling products containing cannabidiol (CBD) in ways that violate the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FDA also published a revised Consumer Update (/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis) detailing safety concerns about CBD products more broadly. Based on the lack of scientific information supporting the safety of CBD in food, the FDA is also indicating today that it cannot conclude that CBD is generally recognized as safe (GRAS) among qualified experts for its use in human or animal food.

Today's actions come as the FDA continues to explore potential pathways for various types of CBD products to be lawfully marketed. This includes ongoing work to obtain and evaluate information to address outstanding questions related to the safety of CBD products, while maintaining the agency's rigorous public health standards. The FDA plans to provide an update on its progress regarding the agency's approach to these products in the coming weeks.

"As we work quickly to further clarify our regulatory approach for products containing cannabis and cannabis-derived compounds like CBD, we'll continue to monitor the marketplace and take action as needed against companies that violate the law in ways that raise a variety of public health concerns. In line with our mission to protect the public, foster innovation, and promote consumer confidence, this overarching approach regarding CBD is the same as the FDA would take for any other substance that we regulate," said FDA Principal Deputy Commissioner Amy Abernethy, M.D.,

Ph.D. “We remain concerned that some people wrongly think that the myriad of CBD products on the market, many of which are illegal, have been evaluated by the FDA and determined to be safe, or that trying CBD ‘can’t hurt.’ Aside from one prescription drug approved to treat two pediatric epilepsy disorders, these products have not been approved by the FDA and we want to be clear that a number of questions remain regarding CBD’s safety – including reports of products containing contaminants, such as pesticides and heavy metals – and there are real risks that need to be considered. We recognize the significant public interest in CBD and we must work together with stakeholders and industry to fill in the knowledge gaps about the science, safety and quality of many of these products.”

Many unanswered questions and data gaps about CBD toxicity exist, and some of the available data raise serious concerns about potential harm from CBD. The revised Consumer Update (/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis) outlines specific safety concerns related to CBD products, including potential liver injury, interactions with other drugs, drowsiness, diarrhea, and changes in mood. In addition, studies in animals have shown that CBD can interfere with the development and function of testes and sperm, decrease testosterone levels and impair sexual behavior in males. Questions also remain about cumulative use of CBD and about CBD’s impacts on vulnerable populations such as children and pregnant or breastfeeding women.

CBD is marketed in a variety of product types, such as oil drops, capsules, syrups, food products such as chocolate bars and teas, and topical lotions and creams. As outlined in the warning letters issued today, these particular companies are using product webpages, online stores and social media to market CBD products in interstate commerce in ways that violate the FD&C Act, including marketing CBD products to treat diseases or for other therapeutic uses for humans and/or animals. Other violations include marketing CBD products as dietary supplements and adding CBD to human and animal foods.

The companies receiving warning letters are:

- Koi CBD LLC (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/koi-cbd-llc-593391-11222019), of Norwalk, California

- Pink Collections Inc. (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mr-pink-collections-llc-593395-11222019), of Beverly Hills, California
- Noli Oil (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/noli-oil-llc-593497-11222019), of Southlake, Texas
- Natural Native LLC (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/natural-native-llc-593385-11222019), of Norman, Oklahoma
- Whole Leaf Organics LLC (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/whole-leaf-organics-llc-593176-11222019), of Sherman Oaks, California
- Infinite Product Company LLLP (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/infinite-product-company-lllp-dba-infinite-cbd-593175-11222019), doing business as Infinite CBD, of Lakewood, Colorado
- Apex Hemp Oil LLC (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/apex-hemp-oil-llc-592691-11222019), of Redmond, Oregon
- Bella Rose Labs (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bella-rose-labs-594246-11222019), of Brooklyn, New York
- Sunflora Inc. (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/sunflora-incthe-cbd-store-llc-dba-your-cbd-store-585390-11222019), of Tampa, Florida/Your CBD Store, of Bradenton, Florida
- Healthy Hemp Strategies LLC, doing business as Curapure (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cdrl-nutritional-inc-593398-11222019), of Concord, California
- Private I Salon LLC (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/private-i-salon-llc-593479-11222019), of Charlotte, North Carolina
- Organix Industries Inc., doing business as Plant Organix (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/organix-

industries-inc-dba-plant-organix-593512-11222019), of San Bernardino, California

- Red Pill Medical Inc. (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/red-pill-medical-inc-593389-11222019), of Phoenix, Arizona
- Sabai Ventures Ltd. (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/sabai-ventures-ltd-593865-11222019), of Los Angeles, California
- Daddy Burt LLC (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/daddy-burt-hemp-co-593866-11222019), doing business as Daddy Burt Hemp Co., of Lexington, Kentucky

The FDA has previously sent warning letters (/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products) to other companies illegally selling CBD products in interstate commerce that claimed to prevent, diagnose, mitigate, treat or cure serious diseases, such as cancer, or otherwise violated the FD&C Act. Some of these products were in further violation because CBD was added to food, and some of the products were also marketed as dietary supplements despite products which contain CBD not meeting the definition of a dietary supplement.

Under the FD&C Act, any product intended to treat a disease or otherwise have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug. The FDA has not approved any CBD products other than one prescription human drug product (/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms) to treat rare, severe forms of epilepsy. There is very limited information for other marketed CBD products, which likely differ in composition from the FDA-approved product and have not been evaluated for potential adverse effects on the body.

Unlike drugs approved by the FDA, there has been no FDA evaluation of whether these unapproved products are effective for their intended use, what the proper dosage might be, how they could interact with FDA-approved drugs, or whether they have dangerous side effects or other safety concerns. In addition, the manufacturing process of unapproved CBD drug products has not been subject to FDA review as part of the human or animal drug approval processes. Consumers may also put off getting important medical care, such as proper diagnosis, treatment and supportive care due

to unsubstantiated claims associated with CBD products. For that reason, it's important that consumers talk to a health care professional about the best way to treat diseases or conditions with existing, approved treatment options.

Additionally, some of the products outlined in the warning letters issued today raise other legal and public health concerns:

- Some of the products are marketed for infants and children – a vulnerable population that may be at greater risk for adverse reactions due to differences in the ability to absorb, metabolize, distribute or excrete a substance such as CBD.
- Some of the products are foods to which CBD has been added. Under the FD&C Act, it is illegal to introduce into interstate commerce any human or animal food to which certain drug ingredients, such as CBD, have been added. In addition, the FDA is not aware of any basis to conclude that CBD is GRAS among qualified experts for its use in human or animal food. There also is no food additive regulation which authorizes the use of CBD as an ingredient in human food or animal food, and the agency is not aware of any other exemption from the food additive definition that would apply to CBD. CBD is therefore an unapproved food additive, and its use in human or animal food violates the FD&C Act for reasons that are independent of its status as a drug ingredient.
- Some of the products are marketed as dietary supplements. However, CBD products cannot be dietary supplements because they do not meet the definition of a dietary supplement under the FD&C Act.
- One product outlined in a warning letter to Apex Hemp Oil LLC is intended for food-producing animals. The agency remains concerned about the safety of human food products (e.g. meat, milk, and eggs) from animals that consume CBD, as there is a lack of data establishing safe CBD residue levels.

The FDA has requested responses from the companies within 15 working days stating how the companies will correct the violations. Failure to correct the violations promptly may result in legal action, including product seizure and/or injunction.

The FDA encourages human and animal health care professionals and consumers to report adverse reactions associated with these or similar products to the agency's MedWatch program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).

The FDA, an agency within the U.S. Department of Health and Human Services, promotes and protects the public health by, among other things, assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

Media:

Peter Cassell (mailto:peter.cassell@fda.hhs.gov)

240-402-6537

Consumer:

888-INFO-FDA

Michael Felberbaum (mailto:michael.felberbaum@fda.hhs.gov)

240-402-9548

Related Information

- What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including Cannabidiol (CBD) (/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis)
- FDA is Committed to Sound, Science-based Policy on CBD (/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd)
- FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD) (/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd)

More Press Announcements (/news-events/newsroom/press-announcements)

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	July 29, 2020
2) Requestor Name	M. Mace
3) Item Title for the Agenda	Licensing Update
4) Should the Item be in Open or Closed Session?	Open
5) Are there Attachments? (If yes, include file names)	No
6) Is a Public Appearance Anticipated?	No

7) Description of the Agenda Item	Presentation at meeting on:
	• Licensing for the 20-21 license year
	• Steps take to make licensing more efficient this year
	  o Waiver of Seal
	  o Use of AAVSB verification

State of Wisconsin
Veterinary Examining Board

Governor Tony Evers
Dr. Robert Forbes, DVM, Chair

April 6, 2020

Applications for Wisconsin Veterinary License

Per Wisconsin Administrative Code ss. VE 3.02(5) and 4.02(5), an applicant for a Wisconsin Veterinary license is required to provide a certificate of graduation that is signed and sealed by the dean of the veterinary school where the person graduated. The certificate of graduation is to be submitted directly to the Veterinary Examining Board by the school.

In recognition of both the Wisconsin Governor's Executive Order #12, Safer at Home, and widespread closures and safer at home orders in other states, due to COVID-19, the Wisconsin Veterinary Examining Board (VEB) will allow either of the following in lieu of, and as a waiver for, a mailed signed and sealed certificate:

- An e-mail, from an official at the veterinary school, with the authority to either attach the certificate or makes the representation that the applicant has successfully graduated from that school of veterinary medicine.
- An e-mail from the American Association of Veterinary State Boards (AAVSB) that it has stored this information in its VAULT program and the applicant has successfully graduated from the indicated school of veterinary medicine.

This waiver shall remain in effect until December 31, 2020.

For any further information on applications, please contact VEB staff, who will be able to answer questions Monday – Friday from 7:45 A.M. – 4:30 P.M. at:

Telephone: 608-224-4353
E-mail: datcpveb@wisconsin.gov

On behalf of the Wisconsin Veterinary Examining Board,

Melissa Mace, Executive Director

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	7/29/20
2) Requestor Name	Angela Fisher
3) Item Title for the Agenda	Under Administrative Code Items: VE 1-11 – Reorganization – Board Approval of Preliminary Public Hearing and Comment Period
4) Should the Item be in Open or Closed Session?	Open Session
5) Are there Attachments? (If yes, include file names)	"VE 1-11 Preliminary Public Hearing Notice" "VE 1-11 Statement of Scope" "VEB Rules Status"
6) Is a Public Appearance Anticipated?	No
7) Description of the Agenda Item	The Governor approved scope statement SS 064-20 on May 15, 2020. On June 16, 2020, the Joint Committee for Review of Administrative Rules directed the VEB to hold a preliminary public hearing and comment period, pursuant to Wis. Stat. § 227.136 (1). This preliminary hearing and comment period will need to be approved by both the VEB and the DATCP Boards. The preliminary hearing and comment period will need to be held before either board can approve the statement of scope. Wis. Stat. s. 89.03 authorizes the VEB to promulgate rules regarding veterinarians and veterinary technicians. However, the authority to determine fees for veterinarians and veterinary technicians is vested in DATCP, pursuant to Wis. Stat. s. 89.063. In addition to VEB approval, the Department will request that the DATCP Board approve this notice at the July 23, 2020, DATCP Board meeting. After the public hearing and comment period, the scope statement will need to go to both boards for approval. The department anticipates bringing the scope statement to the September 24th DATCP Board meeting and the October 21st VEB meeting.

State of Wisconsin
Department of Agriculture, Trade and Consumer Protection
Veterinary Examining Board

NOTICE OF PUBLIC HEARING AND COMMENT PERIOD FOR SS 064-20

Permanent Rule Regarding Licensing, Practice Scope, and Standards of Practice for Veterinarians and Veterinary Technicians

The Wisconsin Department of Agriculture, Trade and Consumer Protection (Department) and Wisconsin Veterinary Examining Board (VEB) announces that, pursuant to Wis. Stat. § 227.136 (1), it has been ordered by the Joint Committee for the Review of Administrative Rules to hold a preliminary public hearing and comment period on its proposed revised statement of scope pertaining to Wis. Admin. Code chs. VE 1-11 regarding licensing, practice scope, and standards of practice for veterinarians and veterinary technicians.

The Department and VEB will hold the public hearing at the time and place shown below. The Department and VEB invites the public to attend the public hearing on the proposed statement of scope or to provide comments on the proposed statement of scope no later than Wednesday, August 26, 2020. Written public comments may be sent to the Division of Animal Health, Department of Agriculture, Trade and Consumer Protection, P.O. Box 8911, Madison, WI 53708-8911 or by e-mail to Angela.Fisher1@wisconsin.gov.

Hearing Date and Location:

Wednesday, August 19, 2020
Commencing at 2:00 PM
Board Room 106, Prairie Oaks State Office Building
Department of Agriculture, Trade and Consumer Protection
2811 Agriculture Drive
Madison, WI 53718

You may obtain a copy of the Statement of Scope for this proposed rule by contacting the Wisconsin Department of Agriculture, Trade and Consumer Protection, Office of the Secretary, P.O. Box 8911, Madison, Wisconsin 53708-8911. You may also obtain a copy by contacting the division policy analyst, Angela Fisher, at Angela.Fisher1@wisconsin.gov or by calling (608) 224-4890. Copies will also be available at the hearing. You can also access the statement of scope online at: https://docs.legis.wisconsin.gov/code/register/2020/774A2/register/ss/ss_064_20/ss_064_20.

Hearing-impaired persons may request an interpreter for this hearing. Please make reservations for a hearing interpreter by August 17, 2020, by writing, calling, or emailing Angela Fisher. The hearing facility is handicap accessible.

Dated this ____day of July, 2020

STATE OF WISCONSIN,
VETERINARY EXAMINING BOARD

By _____

Dr. Robert Forbes, DVM, Chair

Dated this ____day of July, 2020

STATE OF WISCONSIN,
DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By _____

Randy Romanski, Interim Secretary

STATEMENT OF SCOPE

Veterinary Examining Board

Rule No.: Chs. VE 1 to 11, Wis. Admin. Code (Revised)

Relating to: Licensing, Practice Scope, and Standard of Practice for Veterinarians and Veterinary Technicians

Rule Type: Permanent

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

Not applicable.

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

The objective of the proposed rule is to make chs. VE 1 through 11 easier to access and understand quickly.

Fee amounts would not be changed as a part of this proposal. However, the Veterinary Examining Board (VEB) will propose that existing fee amounts be stated in rule to make this information easier to access.

The VEB may propose that the existing eleven rule chapters be consolidated into as few as three chapters, to make it easier to access information for veterinarians, veterinary technicians, and the veterinary professional assistance program.

The VEB proposes that a new chapter be added, to include procedures on discipline that were part of Department of Safety and Professional Services (DSPS) rules pertaining to all DSPS boards but were not transferred to the Department of Agriculture, Trade and Consumer Protection (DATCP) in chs. VE 1 through 11.

The VEB proposes to evaluate rule provisions and language for clarity, consistency, and ease of use, including evaluating procedures and processes, technical changes and updates, delegation of veterinary medical acts, references to relevant statutory requirements, and terminology.

The VEB proposes to evaluate rule language to fulfill the requirements in Wis. Stat. s. 89.078 (2), which requires the VEB to determine by rule what information and documentation a credential holder shall include with a written notice of a conviction.

In response to public comments received during the preliminary public hearing and comment period for SS 125-19, the VEB proposes to evaluate rule language to address the use of telehealth technologies in veterinary medicine and evaluate the circumstances under which a veterinarian may dispense a drug for a patient of another veterinarian.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

Existing Policies Relevant to the Rule

- The current rules, consisting of chs. VE 1 through 11, are denominated as follows:
  1. Authority and Definitions
  2. Examinations

3. Licensure by Examination for Veterinarians
4. Licensure by Endorsement for Veterinarians
5. Practice Related to Veterinary Schools
6. Temporary Consulting Permits
7. Standards of Practice and Unprofessional Conduct for Veterinarians
8. Certification for Veterinary Technicians
9. Standards of Practice and Unprofessional Conduct for Veterinary Technicians
10. Continuing Veterinary Education for Veterinarians and Veterinary Technicians
11. Veterinary Professional Assistance Program

- 2015 Wisconsin Act 55 transferred the VEB from DSPS to DATCP. However, most of the general licensing requirements did not transfer to DATCP in the current chs. VE 1 through 11. This includes rules specifying the procedures and requirements for all boards under DSPS, as well as the fee amounts for VEB fees.

- Current rules refer to the fees required under Wis. Stat. ch. 440, which is the DSPS portion of the statutes, and does not list the dollar amounts of the fees. DATCP has continued to use the same fee amounts that DSPS used, but these amounts are not stated in chs. VE 1 through 11.

- Wis. Stat. s. 89.03 (1) requires the VEB to review the rules at least once every 5 years to determine whether they are consistent with current practice.

New Policies Proposed to be Included in the Rule

- Evaluating whether to state the current fee amounts in rule. Fee amounts would not change.

- Evaluating whether to consolidate the existing eleven chapters.

    - This could include evaluating whether to consolidate the existing rules into as few as three chapters: one for veterinarians, one veterinary technicians, and one for the professional assistance program. Consolidation could make the rules easier to access quickly.

- Evaluating whether to add a chapter for relevant disciplinary procedures that did not transfer in rule from DSPS to DATCP in chs. VE 1 through 11.

- Evaluating whether to make changes regarding procedures and processes.

    - For example, evaluating whether to document a review process for the annual review of colleges and technical schools referenced in ss. VE 1.02 (1e) and 8.01 (1), remove the reference to the review being annual, or make no change.

    - For example, evaluating whether to expand the process under s. VE 3.05 to include applicants who are scheduled to take or are awaiting results from the examination on state laws and rules, document a separate process, or make no change.

- Evaluating whether to make technical changes and updates.

    - For example, evaluating whether to add the denial of a license to the list of reasons for a temporary permit to expire under s. VE 3.05 (6).

    - For example, evaluating whether to permit the electronic submission of the certification of graduation through an online system managed by the American Association of Veterinary State Boards.

    - For example, evaluating whether to provide additional direction in the rules to assure the requirements for access to health care records required in Wis. Stat. s. 89.075 are clear and consistently applied.

- Evaluating whether to allow licensed veterinarians to delegate any additional veterinary medical acts to certified veterinary technicians and/or unlicensed assistants.
    - For example, evaluating whether to modify s. VE 7.02 to allow unlicensed assistants to administer an IV catheter under the direct supervision of a veterinarian present on the premises, per requests from stakeholders.
- Evaluating for consistency and ease of use the places in which rule requirements repeat, or refer to requirements under Wis. Stat. ch. 89. This could include evaluating whether to remove repetitive rule language, refer to the relevant section of statute within the rule text, and use notes to alert the reader to related requirements in the statute, or make no change.
    - For example, unprofessional conduct is listed in Wis. Stat. s. 89.07 and Wis. Admin. Code s. VE 7.06. The rule language repeats some of the items that are listed in statute, but not all. For items that are not repeated, the rule does not refer the reader to the statute through either the rule text or a note. This partial repetition and partial absence can make the rule unnecessarily complex to understand.
    - For example, evaluating the circumstances under which a veterinarian may dispense a drug for a patient of another veterinarian. This would include evaluating when a veterinarian could fill a prescription for the client of another veterinarian.
- Evaluating whether to modify terminology for clarity and consistency.
    - For example, evaluating whether to rename temporary permits (s. VE 3.05) and/or temporary consulting permits (ch. VE 6) to make it easier to distinguish between the different types of permits.
    - For example, evaluating whether to use the word "dispense" rather than "sell" to be more consistent with statutory language and definitions to make the language clearer and easier to understand.
- Evaluating new language to fulfill the requirements of Wis. Stat. s. 89.078 (2), which requires the VEB to determine by rule what information and documentation a credential holder shall include with a written notice of a conviction. The rules do not currently state what information and documentation is required.
- Evaluating new language to address the use of telehealth technologies in veterinary medicine. This would include evaluating under what circumstances it may be appropriate to utilize telehealth technologies in the practice of veterinary medicine versus an in-person physical examination.

Analysis of Policy Alternatives

- Rule Proposal: The existing rules would be evaluated for clarity and ease of use. The fee amounts would remain the same but could be stated in rule to make them readily accessible. Restructuring the chapters could make the rules easier to read and reference quickly. Adding a chapter for relevant procedures could make those procedures clearer and more accessible for credential holders. Evaluating procedures and processes, technical changes and updates, delegation of veterinary medical acts, references to relevant statutory requirements, and terminology could make the rules more consistent and easier to understand. Adding rule language to determine what information and documentation is required in a written notice of conviction from a credential holder would fulfill the requirements of Wis. Stat. s. 89.078 (2). The rule proposal could reduce the burden to veterinarians, veterinary technicians, and consumers of veterinary services, as the rules may become easier to read and understand quickly. The rule proposal would also allow the VEB to respond to public interest to address the use of telehealth technologies in veterinary medicine.
- No Change: Should the VEB not modify the existing rules, the rules would remain unnecessarily difficult to understand. The amounts of fees would continue to be unspecified in rule. Current

requirements relating to veterinarians and veterinary technicians would remain scattered across multiple rule chapters. Some of the board's procedures and processes would remain unclear. The board would not be able to evaluate technical changes and updates or the delegation of veterinary medical acts. References to relevant statutory requirements would remain inconsistent. Some terminology would continue to be unclear and confusing, such as language regarding dispensing versus selling. The rules would continue to not state what information and documentation is required in a written notice of conviction from a credential holder as required by Wis. Stat. s. 89.078 (2). Each of these concerns makes the current rules unnecessarily difficult to understand. The VEB would also not be able to evaluate and respond to public interest to address the use of telehealth technologies in veterinary medicine.

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

Section 89.03, Stats., authorizes the VEB to promulgate rules as follows:

89.03 Rules.

(1) The examining board shall promulgate rules, within the limits of the definitions under s. 89.02 (6), establishing the scope of practice permitted for veterinarians and veterinary technicians and shall review the rules at least once every 5 years to determine whether they are consistent with current practice. The examining board may promulgate rules relating to licensure qualifications, denial of a license, certification, or temporary permit, unprofessional conduct, and disciplinary proceedings.

(2) The examining board shall promulgate rules requiring training and continuing education sufficient to assure competency of veterinarians and veterinary technicians in the practice of veterinary medicine, except that the board may not require training or continuing education concerning the use, handling, distribution, and disposal of pesticides other than for disciplinary purposes.

(3) The examining board shall promulgate rules specifying a procedure for addressing allegations that a person licensed or certified by the veterinary examining board under this chapter has practiced as a veterinarian or veterinary technician while impaired by alcohol or other drugs or that his or her ability to practice is impaired by alcohol or other drugs, and for assisting a person licensed by the veterinary examining board under this chapter who requests to participate in the procedure or who requests assistance in obtaining mental health services. In promulgating rules under this subsection, the examining board shall seek to facilitate early identification of chemically dependent veterinarians or veterinary technicians and encourage their rehabilitation. The rules promulgated under this subsection may be used in conjunction with the formal disciplinary process under this chapter. The examining board may contract with another entity to administer the procedure specified under the rules promulgated under this subsection.4

Section 89.063, Stats., authorizes the Department to determine by rule the fees as follows:

89.063 Fees. The department shall determine by rule the fees for each initial license, certification, and permit issued under ss. 89.06, 89.072, and 89.073, and, if applicable, for renewal of the license, certification, or permit, including late fees, based on the department's administrative and enforcement costs under this chapter. The department shall notify the holder of each such license, certification, or permit of any fee adjustment under this subsection that affects that license, certification, or permit holder.

Section 89.078 (2), Stats., authorizes the VEB to determine by rule what information and documentation a credential holder shall include with a written notice of a conviction:

89.078 (2) A person holding a license, certification, or permit issued under s. 89.06, 89.072, or 89.073 who is convicted of a felony or misdemeanor anywhere shall send a notice of the conviction by 1st class mail to the examining board within 48 hours after the entry of the judgement of conviction. The examining board shall by rule determine what information and documentation the person holding the credential shall include with the written notice.

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

The Department estimates that it will use approximately .5 FTE staff to develop this rule. That calculation includes time required for investigation and analysis, drafting the rule, preparing related documents, coordinating advisory committee meetings, holding public hearings, and communicating with affected persons and groups. The Department will use existing staff to develop this rule.

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

The proposed rule would directly affect Wisconsin licensed veterinarians and certified veterinary technicians. Most veterinary practices are small businesses. Current fee amounts would not change.

The proposed rule may indirectly affect pet and livestock owners who are consumers of veterinary services.

Adjustments to make rule language and structure clearer, and to simplify processes where possible, may reduce the burden to each of these affected entities, by making the rules easier to access and understand quickly.

The VEB held a public hearing on SS 125-19 on February 17, 2020, in Madison, WI. The hearing record remained open until February 24, 2020. The VEB received three comments. All three comments requested that the statement of scope be expanded to address the use of telehealth technologies in the practice of veterinary medicine. One comment also requested that the statement of scope address the circumstances under which a veterinarian may dispense a drug for a patient of another veterinarian. This statement of scope is revised to include both of these topics. No additional entities would be impacted as a result of this revision. Evaluating language regarding telehealth technologies may reduce the economic burden to veterinarians and animal owners in certain circumstances, especially in rural areas.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

Pursuant to 9 CFR 160 to 162, a veterinarian must be specifically authorized by the United States Department of Agriculture – Animal and Plant Health Inspection Service to perform animal disease eradication and control functions under federal animal health laws.

Licensure requirements to practice veterinary medicine are established by each state and should not be affected by federal requirements.

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

The Department expects the proposed rule to have minimal to no economic impact. No fee amounts will be changed in the proposed rule.

Most veterinary practices are small businesses. Adjustments to make rule language and structure clearer may reduce the burden to veterinarians, veterinary technicians, and consumers of veterinary services, as the rules may become easier to access and understand quickly.

Evaluating new language regarding telehealth technologies may reduce the economic burden to veterinarians and animal owners in certain circumstances, in rural areas for example.

Contact Person: Melissa Mace, Executive Director, Veterinary Examining Board; (608) 224-4883

Signed this 1 day of April 2020

Melissa Mace, Exec Director VEB, on behalf of

Dr. Robert Forbes, DVM
Chair
State of Wisconsin Veterinary Examining Board

Signed this 6TH day of APRIL 2020

for Randy Romanski
Interim Secretary
State of Wisconsin Department of Agriculture,
Trade and Consumer Protection

KELLY SMITHBACK
DMS ADMINISTRATOR

DAH Rules Estimated Timelines

Future dates are estimates for the purposes of work planning.
Last Updated: 6/26/20

Key	
White	Estimated date
Blue	Actual date
Yellow	Estimated date requires revision
Red	Projection exceeds deadline (scope expires)

					Statement of Scope										Hearing Draft										Final Draft													
					Initiate	Governor			Preliminary Hearing[1]					Board	Info	EIA[2]		Board		Clearinghouse		Hearing			Board		Governor		Legislature[3]					Adopt	Deadline to Refer to Legis. (Scope Expires)	Rule Effective Date
Rule	Topic	Scope #	DATCP Docket #	Clearing-house #	Begin Scope	Scope to Governor	Governor Approve Scope	Scope Publish in Register	Materials to OS	Board Approve Hearing	Notice Publish in Register	Hearing Date(s)	Record Open Until	Materials to OS	Board Approve Scope	Advisory Comm. Meet	Posted for Comment	Record Open Until	Materials to OS	Board Approve Draft	Refer to CH	Receive CH Comment	Notice Publish in Register	Hearing Date(s)	Record Open Until	Materials to OS	Board Approve Final	Final to Governor	Governor Approve Final	Refer to Legis.	Refer to Comm.	Comm. Review Ends	Refer to JCRAR	JCRAR Review Ends	Rule to LRB		
VE 1-11	Reorg v3 + Tele	SS 064-20			2/24/20	4/7/20	5/15/20	6/8/20	7/2/20	7/23/20; 7/29/20	8/8/20	8/19/20	8/26/20	9/3/20	9/24/20; 10/21/20	11/20/20	1/19/21	3/20/21	7/1/21	7/22/21	7/29/21	8/18/21	8/22/21	9/1/21	9/15/21	11/25/21	12/16/21	12/23/21	2/21/22	3/7/22	3/17/22	5/16/22	5/26/22	7/25/22	8/8/22	12/8/22	10/1/22

Rule Process Step:	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7	Step 8	Step 9	Step 10	Step 11	Step 12	Step 13	Step 14	Step 15	Step 16	Step 17	Step 18	Step 19	Step 20	Step 21	Step 22	Step 23	Step 24	Step 25	Step 26	Step 27	Step 28	Step 29	Step 30	Step 31	Expiration	Step 32
General Projection Assumptions: (specific projections may vary)	Begin process of drafting scope	90 days after Step 1	60 days after Step 2	14 days after Step 3	21 days before Step 6	30 days after Step 4	10 days after Step 6	7 days after Step 7	7 days after Step 8	21 days before Step 11	30 days after Step 9	30 days after Step 11	90 days after Step 11	60 days after Step 13	21 days before Step 16	60 days after Step 14	7 days after Step 16	20 days after Step 17	10 days before Step 20	14 days after Step 18	14 days after Step 20	21 days before Step 23	90 days after Step 21	7 days after Step 23	60 days after Step 24	14 days after Step 25	10 days after Step 26	60 days after Step 26	10 days after Step 27	60 days after Step 29	14 days after Step 30	30 months after Step 4	1-2 months after Step 31
Notes:					7 days OS + 14 days Board	Or next Board meeting	Monday after DATCP submits to publish	At least 3 days after publish in register		7 days OS + 14 days Board	Or next Board meeting	Only some rule packages will have		14, 30, or 60 days	7 days OS + 14 days Board	Or next Board meeting				At least 10 days after publish in register		7 days OS + 14 days Board	Or next Board meeting				Or next session if referred after March in even year	30 days, can be extended to 60 days (+ more if hearing)		30 days, can be extended to 60 days (+ more if hearing)			1st of month after 1 full month

[1]JCRAR may require a preliminary public hearing for the scope statement.
[2]JCRAR may require a separate, independent economic analysis any time between the EIA posting and the Governor's approval of the final draft.
[3]The standing committees and/or JCRAR may take actions, including requiring a meeting/hearing, making germane changes, recalling the rule, and introducing legislation.

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	July 29, 2020
2) Requestor Name	M. Mace
3) Item Title for the Agenda	Strategic Planning
4) Should the Item be in Open or Closed Session?	Open
5) Are there Attachments? (If yes, include file names)	Yes: Full 19 AAVSB 2019 Strategic Planning Presentation Example Montana Strategic Plan Example CVOntario Strategy2023final Example Nevada Strategic Plan Example Washington Strategic Plan Example AAVSB Strategy map Example DAH Strategic Plan 2019-2020
6) Is a Public Appearance Anticipated?	No
7) Description of the Agenda Item	The Board has discussed developing a strategic plan to guide the actions of the board thru turn over. The slides for the presentation that was provided at the 2019 AAVSB meeting, six examples of strategic plans/maps have been provided for review. Melissa Mace will present a very condensed version of the take a ways for strategic planning from the AAVSB meeting. At this meeting of the VEB we will be discussing Vision and Mission of the WI VEB.

2019 AAVSB Annual Meeting & Conference

The Ritz-Carlton Hotel, St. Louis || September 26 - 28, 2019

HOW TO BECOME A STRATEGIC THINKING BOARD

Paul Meyer, President & Co-CEO, Tecker International

AAVSB
AMERICAN ASSOCIATION OF VETERINARY STATE BOARDS

Session Outcomes

- Gain a greater understanding of the value of strategic thinking and planning
- Gain a greater understanding of the processes used for strategic thinking and planning

Leadership is…

- ***Marshalling resources*** – collecting them, focusing their attention and inspiring or empowering their use.
- ***Moving an organization*** – energizing it, removing obstacles to progress, making the changes necessary to improve performance, and enabling it to learn and grow.
- ***The right direction*** – defining the strategies that will have the greatest possible contribution over the long term to the clients or customers that the company was created to serve.

From Leaders Who Make A Difference – Nanus and Dobbs

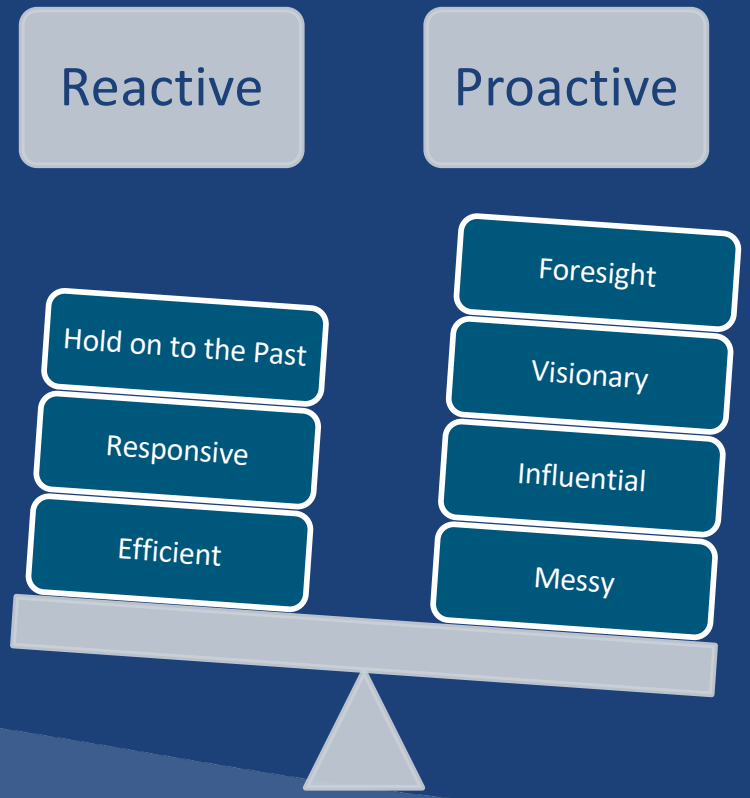
Benefits of Strategic Thinking and Planning

- Creates grounding for board leadership
- Creates a more enjoyable experience
- Assists staff in creating greater alignment
- Creates transformative change

Board's Responsibilities in Strategy

- Set organization's direction
- Align strategy with resources
- Provide oversight

Shift in Strategy



Strategic Thinking Board

- **Generative** – Generative thinking on the part of each board member leads to a more robust organization. Generative thinking helps the board look at patterns and environmental signals.
- **Strategic** – Focus on performance and direction setting. Policy setting and strategic decision making are part of the strategic thinking practice.
- **Fiduciary** – Focus on stewardship and governance, including legal and financial accountabilities. Important aspects of fiduciary thinking are stewardship and representation on behalf of members who elected the board members.

(Chait, Ryan, & Taylor)

Strategic Thinking Board

- Discussion of Mega Issue(s)
- Create, Review and Adjust Strategic Plan
- Policy: Public & Operational
- Routine Board Business

Strategic Thinking Board

- Discussion of Mega Issue(s)
- Create, Review and Adjust Strategic Plan
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Successful Future Planning
✓ *Truly* **strategic** – is distinct from operational planning.
✓ **Responsive** – includes an assessment of environmental conditions is part of the process.
✓ **Focused** – includes a set of focused goals in specific areas.
✓ **A stretch** – includes a longer-term vision stretching the organization beyond its present position.
✓ **Measurable** - includes specific measurements in prioritized areas.

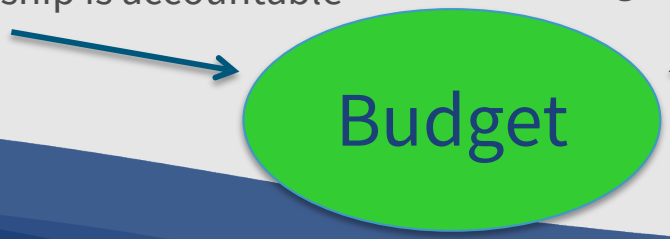
Strategy vs. Operational Planning

Strategic Planning

- Longer-term
- Driven by the vision
- Responsive to external environment
- Alignment of programs and services
- Establishes direction
- Leadership is accountable

Operational Planning

- Annual planning
- Driven by the strategic plan and ongoing operations
- Improvements on existing programs and services
- Establishes work priorities
- Staff and volunteer work groups are accountable



A Process for Planning and Thinking Strategically

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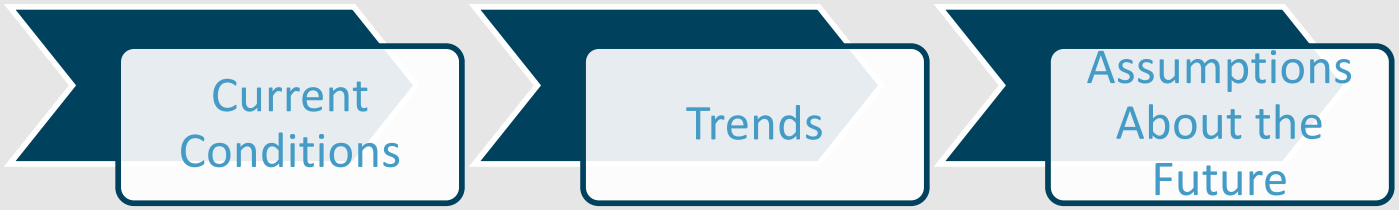
Data Collection: External Environment

5-7 year Planning Horizon
Assessed Annually



Categories of Assumptions

Professional Competition and Structure
Factors affecting competition – current and future. Factors affecting the structure of the industry/profession.

Global Economic Factors
Factors affecting budgets, economic issues, currencies and marketplaces, etc.

Legislation and Regulations
Factors affecting regulation and legislation of our industry/profession, etc. Also consider political "climate."

Demographics, Social Values, and Consumer Preferences
Factors likely to affect lifestyles, values, consumer expectations, aging population, work/family balance, etc.

Technology and Science
Factors identifying possible innovations, advances and disruptions in technology and science.

Key Assumptions

What external assumptions that we believe with have the greatest impact on licensure in the future?

There will be…

A Process for Planning and Thinking Strategically

AAVSB Strategy Map

Created January 2019

AAVSB
AMERICAN ASSOCIATION OF VETERINARY STATE BOARDS

Vision	Mission	Values	Goals	Objectives
The AAVSB is the primary source for comprehensive information that strategically strengthens the veterinary regulatory community.	To support and advance the regulatory process for veterinary medicine.	Protection of the public Reliability & accuracy Ethics & integrity Service excellence Active participation & collaboration Stewardship of resources	**Outreach** The AAVSB is known by strategic audiences as the leader in the veterinary regulatory process.	In the best interest of the AAVSB's mission: • Increase the Member Boards' understanding of the Association • Expand relationships with allied groups • Educate and communicate with domestic and international veterinary and veterinary technology students • Identify opportunities for global growth
			Member Board & Veterinary Community Support The AAVSB is the repository and resource for information and knowledge for veterinary regulatory issues for the benefit of the Member Boards and the veterinary community.	• Increase the efficiency of the pathway to licensure for the Member Boards and the veterinary community and engage stakeholders • Increase the comprehensiveness of the VIVA database • Explore data sharing with the Member Boards and the veterinary community • Ensure appropriate data privacy and security of the VIVA database and all the AAVSB systems
			Policy Leadership The AAVSB will lead in providing direction and resources related to legislative and regulatory matters.	• Increase capabilities to identify, monitor, and develop strategies for future regulatory issues • Increase Member Boards' understanding of the AAVSB's efforts to identify and address future regulatory issues impacting veterinary medicine • Improve and increase the utilization of the AAVSB models for the practice act, rules, regulations, and policies • Increase the Member Boards' understanding of the importance of veterinary paraprofessional regulation related to public safety • Research regulatory resources related to ownership of veterinary practices

Core Ideology *

- The core ideology clarifies what doesn't change for an organization in an environment of rapid and unpredictable change. The core ideology consists of the **Core Purpose (Mission) and Core Values**.
- **Core Purpose** is a concise statement of the organization's reason for being.
- **Core Values** are essential and enduring tenets of the organization - a small set of timeless guiding principles.

** Adapted from Built to Last, Collins and Porras*

Core Ideology

Core Purpose

To solve unsolved problems innovatively.

Core Values

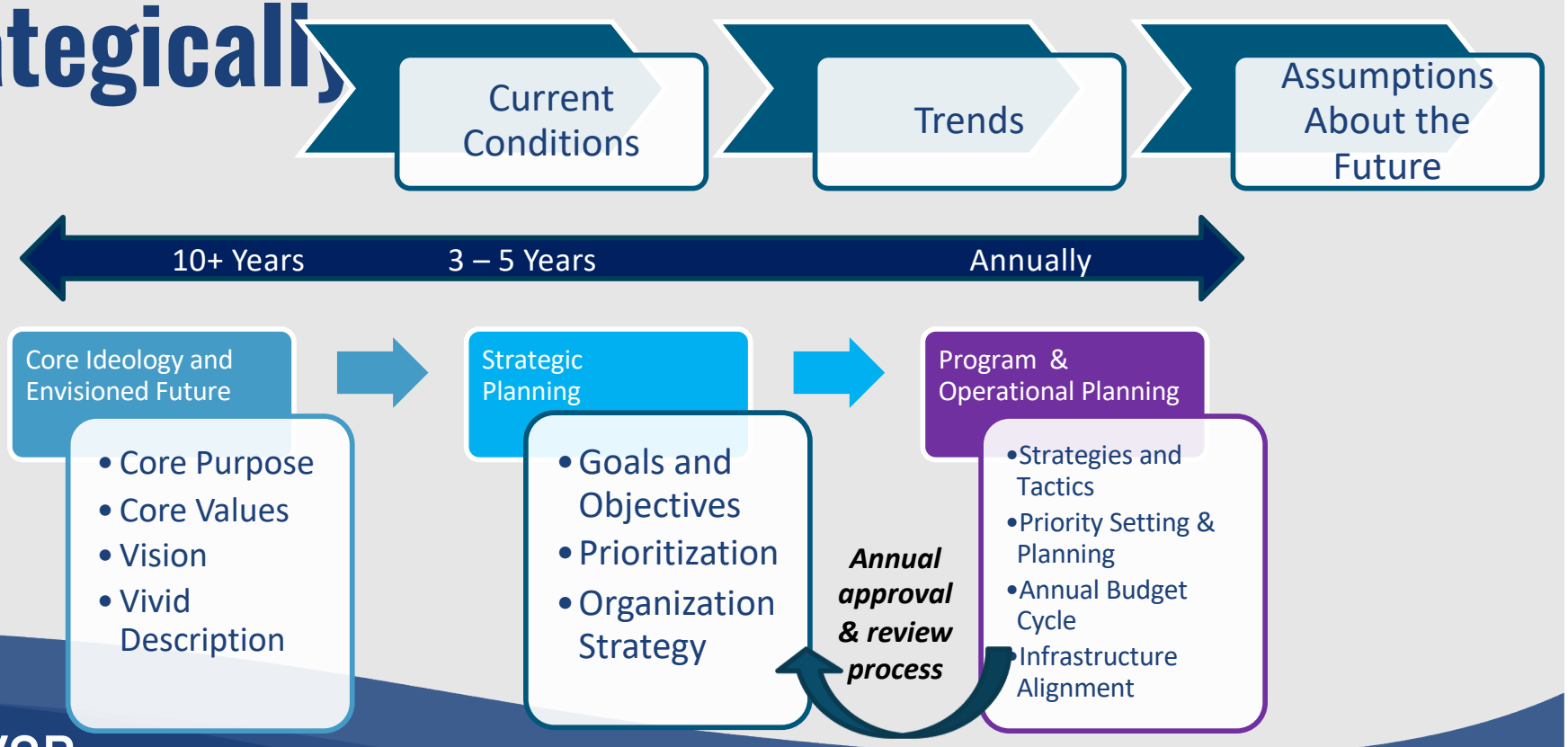
- Absolute integrity
- Respect for individual initiative and personal growth
- Tolerance for honest mistakes

Creating our Core Ideology

Why do we exist (Mission or Core Purpose)?

What are the core behaviors that we should exhibit (Core Values)?

A Process for Planning and Thinking Strategically



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aavsb.org


"Being forward-looking – envisioning exciting possibilities and enlisting others in a shared view of the future – is the attribute that most distinguishes leaders from non-leaders."
Kouzes and Posner, To Lead, Create a Shared Vision,
Harvard Business Review, 2009.

Envisioned Future*

❑ ***10+ Year Vision***

- Huge challenge with a clear finish line.
- Unifying focal point.
- Is aspirational and inspirational.
- Either internally or externally focused.
- Requires significant time to complete.

❑ ***Vivid Description of a Desired Future***

- A vibrant and engaging description of what your "world" would be like if the vision was achieved.
- Paints a picture of the vision.

** Adapted from Built to Last, Collins and Porras*

Draw a picture of your board today if it were depicted as **a form of transportation.**

Identify organizational attributes represented by your picture.

Draw a picture of your "dream" board 10 years from now if it were depicted as **a form of transportation.**

Identify organizational attributes represented by your picture.

Current

Future

Creating Our Vision

Identify a one sentence future vision:

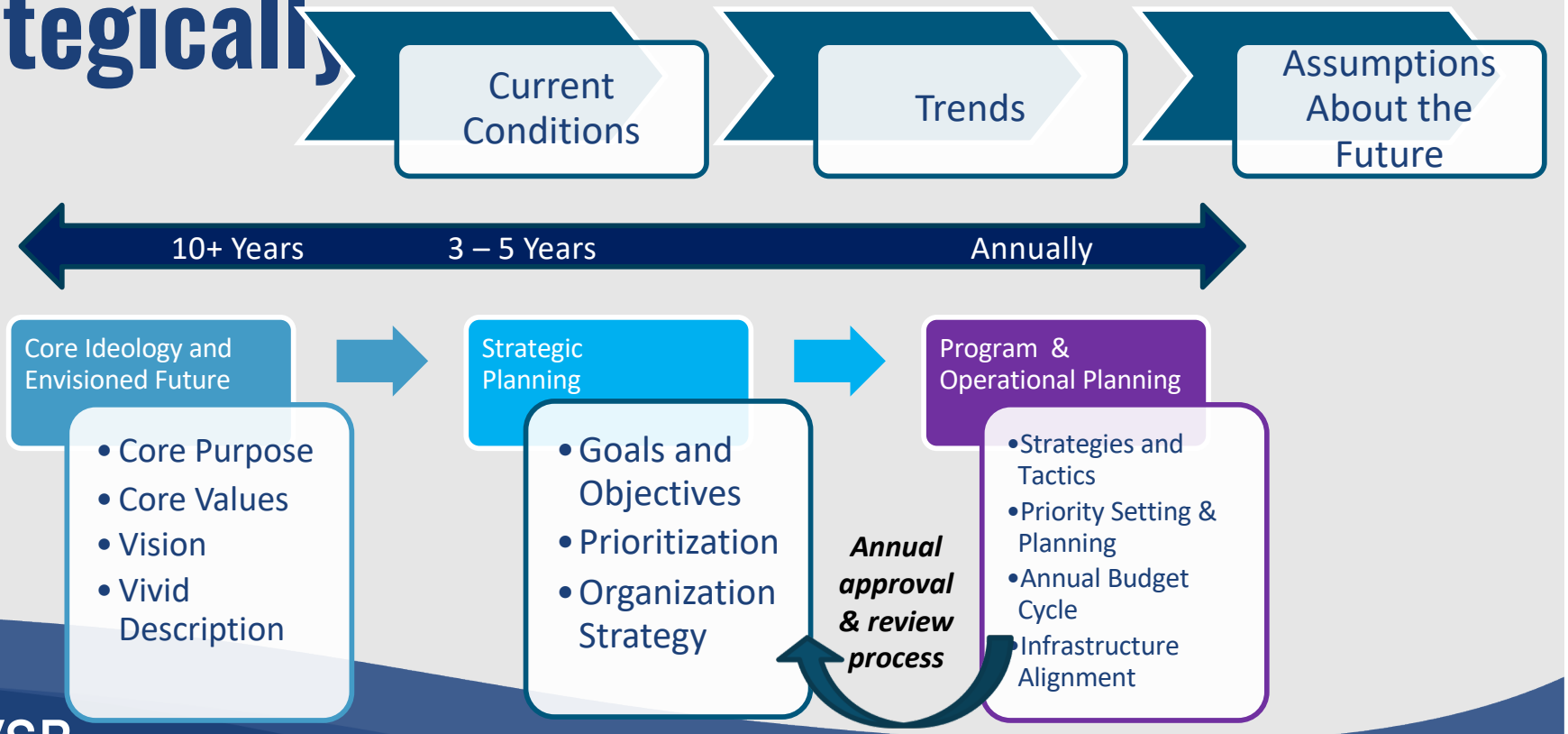
Vivid Description of a Desired Future

- Vibrant, engaging description of what it will be like to achieve the Vision.
- Passion, emotion, and conviction are essential to Vivid Descriptions.

Henry Ford:

I will build a motor car for the great multitude… It will be so low in price that no man making a good salary will be unable to own one-and enjoy with his family the blessing of hours in God's great open spaces… When I'm through, everyone will be able to afford one… the horse will have disappeared from our highways, the automobile will be taken for granted, and a large number… will be employed at good wages….

A Process for Planning and Thinking Strategically



Shorter-term Planning Horizon

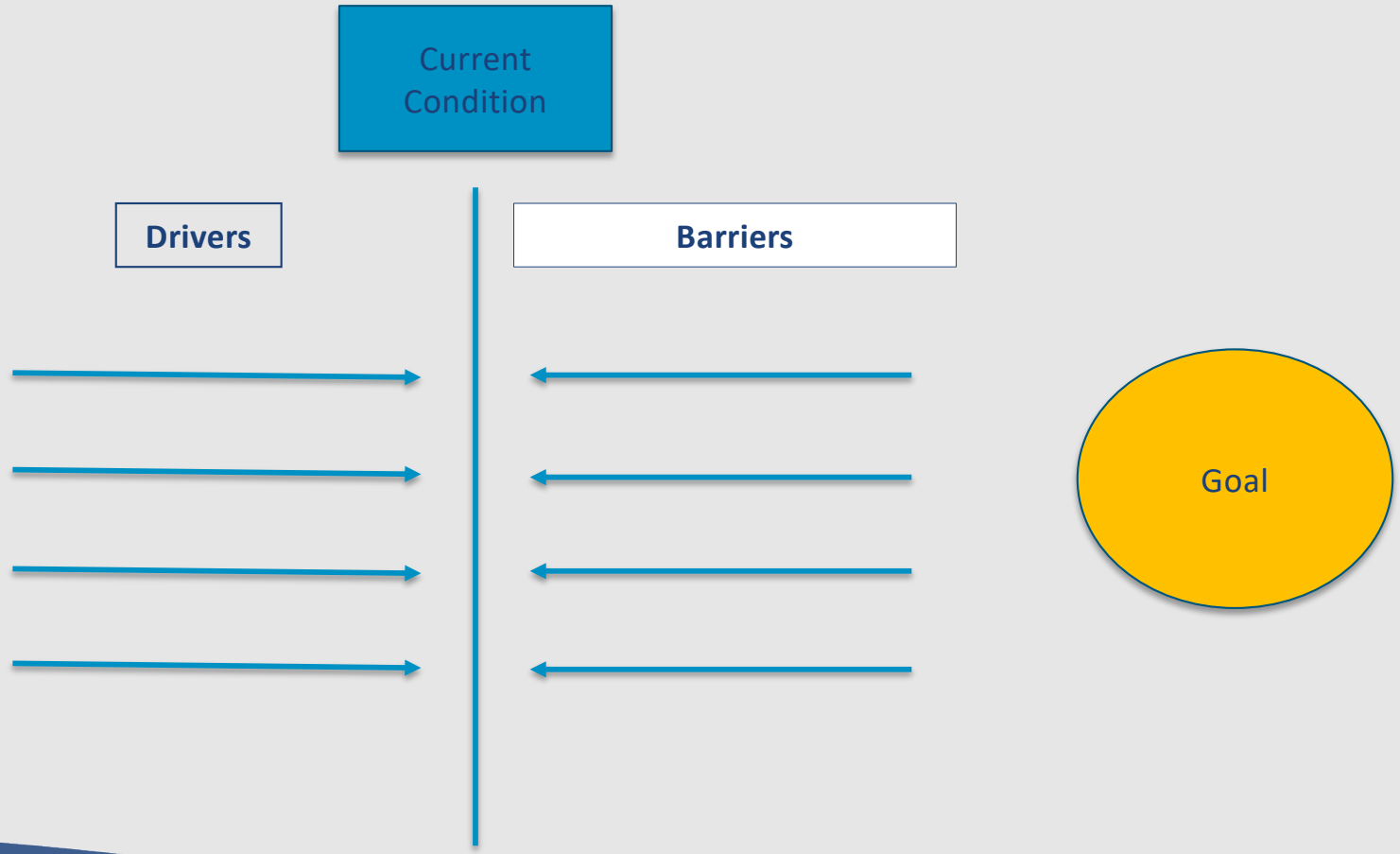
Goals (3-5 years): Outcomes the enterprise is committed to achieving. Reviewed annually.

Objectives (3-5 years): Desired direction the enterprise needs to move in to accomplish its goals. What would constitute success in observable or measurable terms?

Increase… Decrease…

Eliminate… Maintain…

Enhance/Improve… Achieve…


Current Condition
Drivers
Barriers
Goal

Setting Priorities

(I) = Must begin objective in next fiscal year

(M) = May begin objective, if resources permit, in next fiscal year

(L) = Begin objective in subsequent fiscal year

Strategies (Activities)

- ❑ Describe how the organization will commit its resources to accomplishing work toward the goal.
- ❑ Serve as a link from long-term planning to annual planning.
- ❑ Become part of the budgeting process.
- ❑ Set accountability and strategic priorities for staff and volunteer groups.

Strategies (Activities)

Considerations:

- Continuation and/or enhancements to ongoing activities.
- “Gaps” requiring new initiatives.
- Are we going to do less of anything?
- Who is accountable and who needs to be involved?
- What are the resource implications?

Characteristics of Successful Implementation

Clear and compelling strategic direction.

Commitment to strategic direction at all levels.

Commitment to working across functional and product-line silos.

Alignment of plan to activities.

Appropriate ongoing review at all levels – Board and staff.

Integration of plan, where appropriate, into accountability and evaluation systems.

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Strategic Thinking Board

- Discussion of Mega Issue(s)
- Create, Review and Adjust Strategic Plan
- Policy: Public & Operational
- Routine Board Business

What is a "Mega Issue?"

…overriding issues of strategic importance

Address key strategic questions/challenges

Could relate to profession or certification process

Considered in a three-year planning horizon

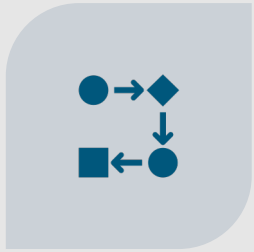
Requires deep conversation to take action

Four Important Elements

Formulate the question

Practice knowledge-based decision-making

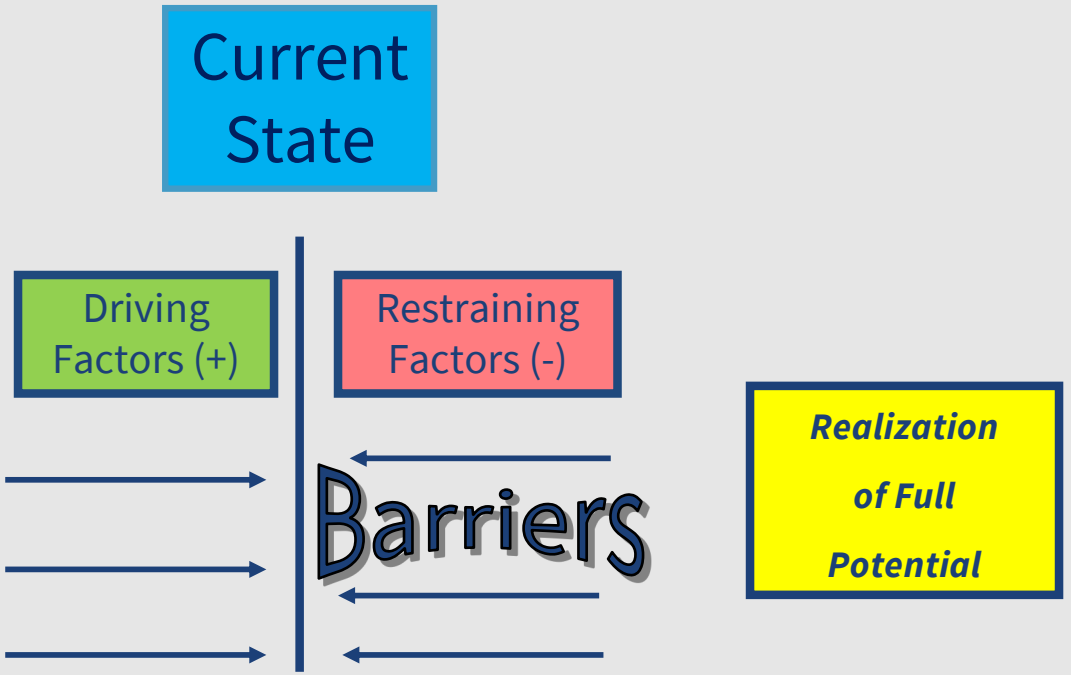
Practice dialogue before deliberation



Move from deliberation to decision-making

Formulate the Question

- Should not be easily answered with “yes” or “no”
- “How…?” and “What…?”



Question 1: _____

Question 2: _____

Question 3: _____

Three Step Process

Four Knowledge Bases

What do we know about our stakeholders **needs, wants and preferences** that is relevant to the decision?*

What do we know about the **current realities and evolving dynamics** of our environment that is relevant to this decision?*

What do we know about the **"capacity" and "strategic position"** of our organization that is relevant to this decision?*

What are the **ethical implications?**

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** What do we wish we knew, but don't?*


STRATEGIC POSITION:
factors in the external environment including competitors and dynamics the organizations cannot control
CAPACITY:
tangible and intangible assets of the organization

Mega-Issue Question:

What do we know about needs and preferences?	What do we know about current realities and evolving dynamics?	What do we know about capacity and strategic position?	What do we know about ethical implications?

Three Step Process

Define what is known about the issue

Identify and assess strategy choices

Determine what action will be taken

Strategic Choices

"**Choice**" - *a discrete, but not necessarily mutually exclusive, alternative*.

1. Do nothing
2. Do something
   - **What are the possible "some-things?**

Strategic Choices

1.
2.
3.
4.

Strategic Choice:

Advantages	Disadvantages

Strategic Choice:

Advantages	Disadvantages

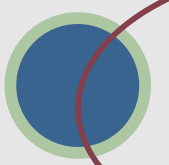
Strategic Choice:

Advantages	Disadvantages

Three Step Process

Define what is known about the issue

Identify and assess strategy choices



Determine what action will be taken

Identify Actions, Intent and Accountability

- What actions does this choice (or need for additional information) suggest about who needs to do what?
- What are the implications for the board and staff?
- Who will task whom for what? Who will be accountable?

Paul D. Meyer

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Paul D. Meyer is President and Co-CEO with Glenn Tecker of Tecker International, LLC, and Principal Consultant with Thunderbolt Thinking, Inc. providing strategy development and change management consulting, strategic planning, issue resolution facilitation, organizational governance, innovation training, operational analysis, board/volunteer leadership development, and research for corporations and not-for-profit organizations.

Consulting Experience

For the past 10 years, Paul has worked with associations, NGOs, academic institutions, and corporations' worldwide as well as state, province, and local component organizations and community-based institutions representing a variety of industries, professions and causes. He has worked with groups in a number of settings such as medical, hospitality, education, mental health, accounting, state governments, construction, travel, engineering, pharmacy, trucking, scientific research, library sciences, public institutions, entertainment, technology, and insurance/financial services. His primary areas of expertise include strategic planning facilitation and implementation, knowledge-based decision-making, conflict facilitation and mediation, brand positioning, operational analysis, structural reengineering, market and marketing research, governance restructuring, and product/program assessments. He is a proven researcher, trainer, and group process facilitator focused on producing results through collaboration, group dialogue, decision-making processes, and research assessment. Paul's skills and experience enables him to assist groups at reaching consensus in developing new opportunities, creating innovative solutions, solving problems, and achieving identified organizational goals. His recent accomplishments include:

- Reengineered long-standing governance structures in response to changing volunteer preferences and organizational needs.
- Designed and facilitated future visioning forums convened to rethink and reshape professions and industries.
- Strategically positioned public institutions to successfully navigate changing consumer priorities and needs.
- Redesigned organizational infrastructures in response to strategic priorities.
- Assessed program portfolios in order to strategically align activities with direction.
- Provided interactive leadership development sessions motivating and educating volunteers.

Education and Professional Involvements

Paul has an MBA from Marymount University and has earned his Certified Association Executive (CAE) designation from the American Society of Association Executives (ASAE). Paul has been a faculty member of the US Chamber of Commerce's Institute for Organizational Management and currently a content leader for ASAE's CEO Symposiums.

Paul is co-author of the best-selling book The Will to Govern Well: Knowledge, Trust and Nimbleness

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Questions?

For the best experience, open this PDF portfolio in Acrobat X or Adobe Reader X, or later.

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2020-2023

Strategic Plan

Vision

Instilling public confidence in veterinary regulation

Mission

Governing the practice of veterinary medicine

Principles

Honest
Reliable
Competent
Relevant
Independent
Inclusive
Accountable

Strategic Objectives

- ❒ Promoting professionalism to assure quality care.
- ❒ Modernizing the oversight of the veterinary profession.
- ❒ Regulating proactively to mitigate risks.
- ❒ Championing One Health.
- ❒ Assuring impact through outcomes.

CVO
THE COLLEGE OF VETERINARIANS OF ONTARIO

Strategy 2023

Year One Tactics

Promoting professionalism to assure quality care.

- ❒ Plan and promote a pilot of a new model of facility accreditation.
- ❒ Launch the Peer Advisory Conversation as a voluntary veterinary quality assurance tool.
- ❒ Create a resource hub for veterinary discussion on ethical issues.
- ❒ Publish resources on conflict of interest and professional practice.
- ❒ Develop discussion on the concept of "standard of care".
- ❒ Partner with North American leaders to develop an essential competency profile for veterinary medicine.

Modernizing the oversight of the veterinary profession.

- ❒ Identify key areas achievable with regulation changes as a primary target.
- ❒ Consider opportunities to test telemedicine delivery models of the future under safeguarded conditions.
- ❒ Seek multi stakeholder discussions to continue the aim to achieve commitment to full legislative reform.

Championing One Health.

- ❒ Set a next animal welfare agenda.
- ❒ Establish a stakeholder relationship with public health in Ontario.
- ❒ Implement a communication and education strategy highlighting veterinarians as public health practitioners.
- ❒ Explore the definition of one welfare and its relevance to this objective.

Assuring impact through outcomes.

- ❒ Educate Council and staff on the new outcomes focused regulation framework.
- ❒ Establish an impact strategy unit.
- ❒ Coordinate the work on impact with the Risk Analysis and Mitigation Unit.
- ❒ Implement the use of the framework with all new policy direction.

Regulating proactively to mitigate risk

- ❒ Collaborate internationally on the future of technology, veterinary medicine and competence.
- ❒ Consider options to safely broaden remote dispensing beyond antimicrobial drugs.
- ❒ Set work plan for establishing competence assessment that supports limited licensure.
- ❒ Analyze past decisions and make recommendations on how to best mitigate practice management concerns separate from veterinary medicine.
- ❒ Identify strategies to improve veterinary drug management.

2019	Deployment
Address Statutory Changes for 2021 Legislative Session	Completed December 2019 (Two possible bill drafts)
Update Website and Database	Due for completion July, 2019. Vendor released from contract due to non-delivery of goods.
Analyze Statutory Requirements for Streamline Licensure Process	Completed December 2019
Analyze needs of Telehealth/Teletriage in Nevada	Completed January, 2019
Review policies for hearing protocols	Completed April, 2019

2020	Deployment
Full NRS Chapter Review	Completed January, 2020
Statutory Change Language for 2021 Legislative Session	Completed April 2020
Increase End User Access to Licensing and Renewal Portal (database services)	July 2020
Increase Website Accessibility through Portal Rebuilt with Ektron	July 2020
Increase Hospital Inspection compliance with cite and fines for repeat offences	June 2020
Development of monthly bulletin for faster response to emerging licensee issues (medical, communication, and public responses)	Deployed April 1, 2020
Public documents for advice on dealing with communication issues, records request, questions about veterinary practice/protocols	August, 2020
Licensee Survey	October, 2020

2021	Deployment
Develop/update investigation protocols	October 2021
Fully online application process	October 2021
Northern and Southern Nevada Consumer Survey	January 2021
Develop inspection protocols and education initiatives with Board of Pharmacy	February, 2021

VETERINARY BOARD OF GOVERNORS

2019 – 2020 BUSINESS PLAN

Goals

1. **Priority Rule Making:** By the end of 2019 complete the rule writing process for the below three areas.
   a. Client Consultation
   b. Vet-Tech CE
   c. CCT

2. **Telemedicine:** By the end of 2019 provide a guidance document to all veterinarian practitioners concerning telehealth.

3. **Cannabis / CBD Usage:** By the end of 2019 the Board will receive legal options concerning Cannabis.

DOH Mission: The Department of Health works with others to protect and improve the health of all people in Washington State.

Veterinary Board Mission: The mission of the Veterinary Board is to protect the public and animals' health and safety, and to promote the welfare of the state by regulating the competency and quality of healthcare providers.

Veterinary Board Vision:

The Veterinary Board of Governors' vision is to be the trusted leader in protecting and improving the health of all the animals and the public across Washington State.

Veterinary Board Values:

- Integrity – Core Value
- Respect – Core Value
- Fairness – Core Value
- Proactivity – Aspirational Value
- Empathy – Core Value

What We Do: The Veterinary Board of Governors is made up of five licensed veterinarians, one licensed veterinary technician, and one public member, all appointed by the governor. The Veterinary Board protects the public and animal's health numbering over 4.1 million pets and households across all of Washington.

2020 Goals

To Be Developed at the Strategic Plan Retreat – March 3rd, 2020.

2019 Goals

Goal 1 - Priority Rule Making: By the end of 2019 complete the rule writing process for the below 3 areas.

- Client Consultation (Priority) – **Hearing in March 2020**
- Vet-Tech CE Rule – **Filed and Completed**
- CCT – **Filed and Completed**

Goal 2 - Telemedicine – Guidance Document: By the end of 2019 provide a guidance document to all practitioners concerning telehealth.

  - Research federal Level
  - Research local level
  - Surveys
  - AVSB
  - Take WMC verbiage and draft guidelines
  - VBOG Sub-Committee

Goal 2 was not completed. Move to 2020?

Goal 3: Cannabis / CBD Usage - By the end of 2019 Chris will provide legal opinion during the September Board Meeting. By the end of 2019 the Board will receive legal options concerning Cannabis. (This is a priority over telemedicine.)

Pending 2 pieces from Chris (AG) and the Federal Government. Cannabis is in flux at this point. Chris and the Board developed a statement for all Veterinarians on the DOH website.

2018 Goals

Goal 1: Perform two (2) educational events to discuss the functions and process of the board in 2018.

Objectives: Updated
Needed Events:

1. **WSVMA Power of 10** – Loralei presented information about the board, its roles, and recent activities.
   COMPLETE. ONGOING

2. **WSVMA Sept 2018 Conference –** DOH attorney (Marlee), Loralei, and Sue presented on the Veterinary Track: **Disciplinary process and new CE requirements COMPLETE. ONGOING**

3. **WSVMA Sept 2018 Conference –** Michelle and Kim presented on the Veterinary Technician Track: **VBOG – Who are we and what do we do? COMPLETE, ONGOING**

4. **WSU Event –** Michelle to research; Liz and Kirk to present.
   Board was not able to present at this event. Goal Completed.

Goal 2: By the end of 2018, complete the CE Rule and audit tracking mechanism.

Objectives: Develop a tracking tool to update the board on the status of CE audits.

1. **CE Audit Tracking Tool –** Loralei developed a tracking tool and updates the board twice yearly on the percentage of failed audits (which can be broken down by veterinarian and technician).
   ONGOING – BOARD is still working through CE Audits. Move to 2020?

Goal 3: Develop and create a welcome to the Veterinary Board package for all members new and current by the end of 2018.
ONGOING

AAVSB Strategy Map

Created January 2019

AAVSB
AMERICAN ASSOCIATION OF VETERINARY STATE BOARDS

Vision	Mission	Values	Goals	Objectives
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Department of Agriculture, Trade and Consumer Protection

Division of Animal Health

2015-2020 Strategic Plan

Updated April 2019

Vision

Setting the standard for animal health, welfare, and trade nationwide.

Mission

To safeguard animal health, public health, and animal industries in Wisconsin utilizing the best available science and public policy.

Core Values AH Spirit

- **S** — **Stewardship:** We are committed to making decisions that will ensure the long-term survival of agriculture. We are committed to maximizing the value of our human, financial, and physical resources.
- **P** — **Professionalism:** Our staff maintain professional standards of practice and ethics and act in the best interest of the agency and the public.
- **I** — **Initiative:** We are compelled by our own ambition and the responsibility to those we serve to attain success in the performance of our duties.
- **R** — **Respect:** We hold each other and those that we serve in esteem and recognize the contributions of others.
- **I** — **Integrity and Honesty:** We are honest, transparent, ethical, and objective in all that we do.
- **T** — **Team:** In all things we do, we recognize that our combined efforts yield the best results.

Core Strategies

The following core strategies organize our resource allocation and work effort in the Division of Animal Health. We will focus on key performance objectives each year within these core strategies in order to meet our mission and vision for enhancing animal health in Wisconsin.

Key Performance Objectives

Disease Management

Continuously improve our ability for rapid detection, control and eradication of animal diseases affecting animal and public health.

I. Enhance disease *prevention* by:
   A. Presenting quarterly disease- or program-focused internal webinars.
   B. Implementing agency-wide biosecurity plans.
      1. Finalize policy.
      2. Develop an audit plan to ensure staff are maintaining biosecurity.
      3. Develop a biosecurity training plan.

II. Enhance disease *detection* by:
   A. Reviewing how reportable diseases are reported and how this information is managed.
   B. Providing outreach about reportable disease reporting after rule finalized.
   C. Creating quarterly newsletter focused on concerns.

III. Enhance our capabilities for disease response by:
   A. Creating a template for a final epidemiological report that captures the entire incident and includes an executive summary.
   B. Providing refresher training as needed for base Incident Command System and emergency response preparedness by AH position type.
   C. Evaluating data management of traceability and case management. Conduct lean project to evaluate current systems and options. Hold until 2020, then assign a lead coordinator.
   D. Conducting an analysis of trace investigations, challenges/ impediments, and cost.

Collaboration with Industry and Animal Health Partners

Improve collaboration, strengthen relationships and build partnerships among all stakeholders in Animal Health.

I. Design and implement a plan to increase public outreach by using multiple formats of communication from social media, websites, in-person presentations, and other traditional channels.
   A. Creating and sharing informational presentations to be given by field or office staff. Develop process to make widely available (as appropriate) and keep updated.
      1. Including education about swine rules prior to fair season.
   B. Develop and share quarterly animal health newsletter.

II. Identify and work with public and private partners where there are shared priorities and work together to accomplish those common goals in a more efficient and holistic fashion resulting in a more coherent communication to affected industries.
   A. Revise the events database to be more effective in capturing events staff participate in and documenting the outcome.
   B. Develop advisory committees related to the following topics:
      1. Cattle health
      2. CWD/deer
      3. Appropriation 234
      4. Appropriation 236
   C. Be actively involved with industry, participate in councils, and maintain a list of councils.

Technological and Operational Excellence

Analyze our resources and operation procedures to address needs with an eye to the future.

I. Proactively work with appropriate committees and teams to identify methods to increase availability and understanding of job tools.
   A. Explore the need and benefit of a compliance-specific UEG.
   B. Maintain CRM guidance and pursue changes to CRM that make sense utilizing the CRM user group as appropriate or creating enhancement requests for DAH-specific requests.

II. Develop and implement investigatory standards for field staff.

III. Implement a basic intranet DAH SharePoint structure and management plan.

IV. Evaluate use of EMRS software, identify staffing needs, and provide EMRS training as appropriate to support daily operations and emergency preparedness for trace investigations.

V. Evaluate need for MIM training based on how many staff can or should be able to do all MIM and PDA tasks.

VI. Evaluate CORE1 for potential use with other AH programs.
   A. Evaluate options for Johne's data, such as CRM or CORE1.

Employee Development

Support all staff in attaining levels of professional effectiveness through an investment in providing the right training, tools, and creating opportunities for leadership.

I. Identify critical functions, such as MIMS and EMRS, where cross training is necessary; devise a plan to achieve cross training; and begin implementation of cross training in those critical functions.

II. Identify training opportunities for SMEs.

III. Develop office staff training plans.

IV. Conduct survey about the following topics:
   A. DATCP survey results: I have sufficient resources (people, materials, budget) to get my job done. (24% disagree/strongly disagree). Ask for more information about types of resources.
   B. Ways to recognize staff work and achievement.

V. Review and update all position descriptions and KSA's (knowledge skills and abilities) to ensure readiness for recruitment and address operational needs.

Animal Welfare

Provide continuous awareness for staff and stakeholders on appropriate handling of animals and continue to be a resource for guidance and education on humane care for all animals.

I. Provide exemplary animal care during field investigations involving animal handling by ensuring that staff receive sufficient training related to animal handling and humane care of animals.

II. Ensure that animal handling training is incorporated in routine staff trainings.
   A. Maintain sustainable, recurring, animal handling refresher training program.
   B. Explore need for specialized Animal Welfare education on a recurring basis.
      1. Humane euthanasia training

III. Document and refer to the appropriate jurisdiction all instances when inhumane handling of animal is observed.

WI VEB STRATEGIC PLANNING

Goals for Today

- General understanding of what a strategic plan is
- Start VEB members thinking about what the VEBs Strategic plan should look like.
- What duration should it cover

- Prepare the board to draft initiate a draft Strategic Plan, in Oct., starting in 2021.

WHY PLAN?

- Creates grounding for board leadership
- Assists in more seamless transition of board leadership
- Creates a more enjoyable experience
- Assists staff in creating greater alignment
- Creates transformative change

Successful Future Planning

- ***Truly* strategic** – is distinct from operational planning.
- **Responsive** – includes an assessment of environmental conditions is part of the process.
- **Focused** – includes a set of focused goals in specific areas.
- **A stretch** – includes a longer-term vision stretching the organization beyond its present position.
- **Measurable** - includes specific measurements in prioritized areas.

Process for Strategic Planning

- Long Range (10+ years)
  - Envisioned Future
    - Vision
  - Core ideology
    - Mission (Core Purpose)
    - Core Values
- Mid range (3-5 years)
  - Strategic Planning
    - Goals and Objective
    - Organizational Strategy
- Short term (annual)
  - Operational plans
    - Tactics Strategy, priority setting and planning to accomplish Strategic Goals.

Vision

- A vivid description of a Desired Future
- Challenge with a clear finish line
- Unifying focal point
- Aspirational and inspirational
- Requires significant time to complete

- EXAMPLES:
  - AAVSB: The AAVSB is the primary source for comprehensive information that strategically strengthens the veterinary regulatory community.
  - CVO: Instilling public confidence in veterinary regulation.
  - DAH: Setting the standard for Animal Health, Welfare, and Trade nation wide.
  - Washington: … to be the trusted leader in protecting and improving the health of all the animals and the public across Washington State.

MISSION (CORE PURPOSE) AND CORE VALUES

- The core ideology clarifies what doesn't change for an organization in an environment of rapid and unpredictable change. The core ideology consists of the Core Purpose (Mission) and Core Values.

Mission (Core Purpose)

- **Mission** (Core Purpose) is a concise statement of the organization's reason for being.

  - AAVSBs: To support and advance the regulatory process for veterinary medicine.
  - CVO: Governing the practice of Veterinary Medicine
  - Washington: The mission of the Veterinary Board is to protect the public and animals' health and safety, and to promote the welfare of the state by regulating the competency and quality of healthcare providers.
  - DAH: To safeguard animal health, public health, and animal industries in Wisconsin utilizing the best available science and public policy.

Core Values

- **Core Values** are essential and enduring tenets of the organization -a small set of timeless guiding principles.

  - DAH: Stewardship, Professionalism, Initiative, Respect, Integrity, Team
  - Washington: Integrity, Respect, Fairness, Proactivity, Empathy
  - CVO: Honest, Reliable, Competent, Relevant, Independent, Inclusive, Accountable
  - AAVSB: Protection of the public, Reliability and Accuracy, Ethic and integrity, Service Excellence, Active participation and collaboration, Stewardship of resources

Goals and Objectives

- **Goals (3-5 years):** Outcomes the enterprise is committed to achieving. Reviewed annually.
- **Objectives (3-5 years):** Desired direction the enterprise needs to move in to accomplish its goals. What would constitute success in observable or measurable terms?
  - Increase… Decrease…
  - Eliminate… Maintain…
  - Enhance/Improve… Achieve…

Mega Issues

- Discussion on these help set your strategic Goals/Objectives
  - Examples:
    - Telemedicine
    - Cannabis
    - Veterinary Shortage