

# UVM Project ECHO:Dental Series Treatment of Oral Health-Related Pain

## August 13, 2021

Course Director: Justin Hurlburt, DMD, MA  
ECHO Director: Elizabeth Cote

Series Faculty: Charles D. MacLean, MD  
Amanda Kennedy, PharmD, BCPS  
Hannah Hauser, MSW  
Jeffrey Crandall, DDS  
Natalia Chalmers, DDS, MHSc, PhD  
Raymond Dionne, DDS, PhD  
Sue Etminan, DMD, MPH  
Thomas Connolly, MDM

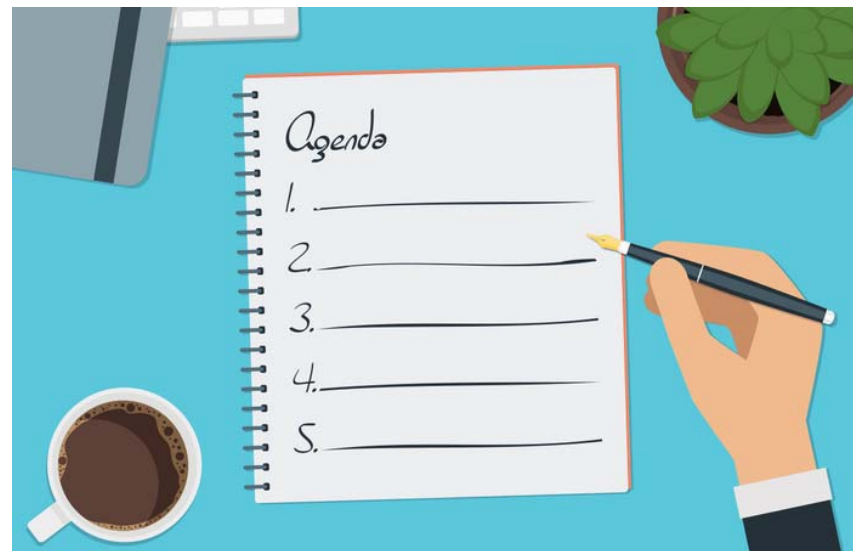


- RECORDING OF SESSION TO BEGIN



# Agenda

- Introductions
- Objectives
- Didactic Presentation (15-20 min)
- Case presentation
  - Clarifying questions
  - Participants – then faculty panel
- Discussion
- Recommendations
- Summary
- Closing Announcements
  - Submission of new cases
  - Completion of evaluations



## CE Disclosures

The Vermont Board of Dental Examiners (BDE) designates this internet live activity for a maximum of 1.0 Continuing Education (CE) Credit. Participants should claim only the credit commensurate with the extent of their participation in the activity.

### Interest Disclosures:

- As an organization accredited by the ACCME to sponsor continuing medical education activities, UVM is required to disclose any real or apparent conflicts of interest (COI) that any speakers may have related to the content of their presentations.



# Series Objectives

At the end of this ECHO series participants will:

- Understand the best practice approach to prescribing opioids for pain
- Be able to implement a workflow for the use of the Vermont Prescription Monitoring System (VPMS), including the use of delegates
- Understand the evaluation and management of patients with substance use disorder
- Identify and understand common causes of chronic orofacial pain and their connection to dentistry
- Understand effective non-opioid options for the management of pain in dental practice



# Fundamentals of FDA Regulations of Oral Health Products and US Trends for Opioid and Antibiotic Prescribing in Dentistry

Dr. Natalia Chalmers DDS, MHSc, PhD  
and Dr. Frederick Hyman, DDS, MPH  
Division of Dermatology and Dentistry,  
Center for Drug Evaluation and Research, FDA



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# Session Objectives

By the end of this activity, the learners should be able to:

- The participants will understand the steps of bringing a new drug into the marketplace and monitoring its safety.
- The participants will describe opioid and antibiotic pediatric prescribing trends and identify policies that impact clinical practice, antibiotic and opioid stewardship



# Fundamentals of FDA Regulations of Oral Health Products

Dr. Frederick Hyman, DDS, MPH



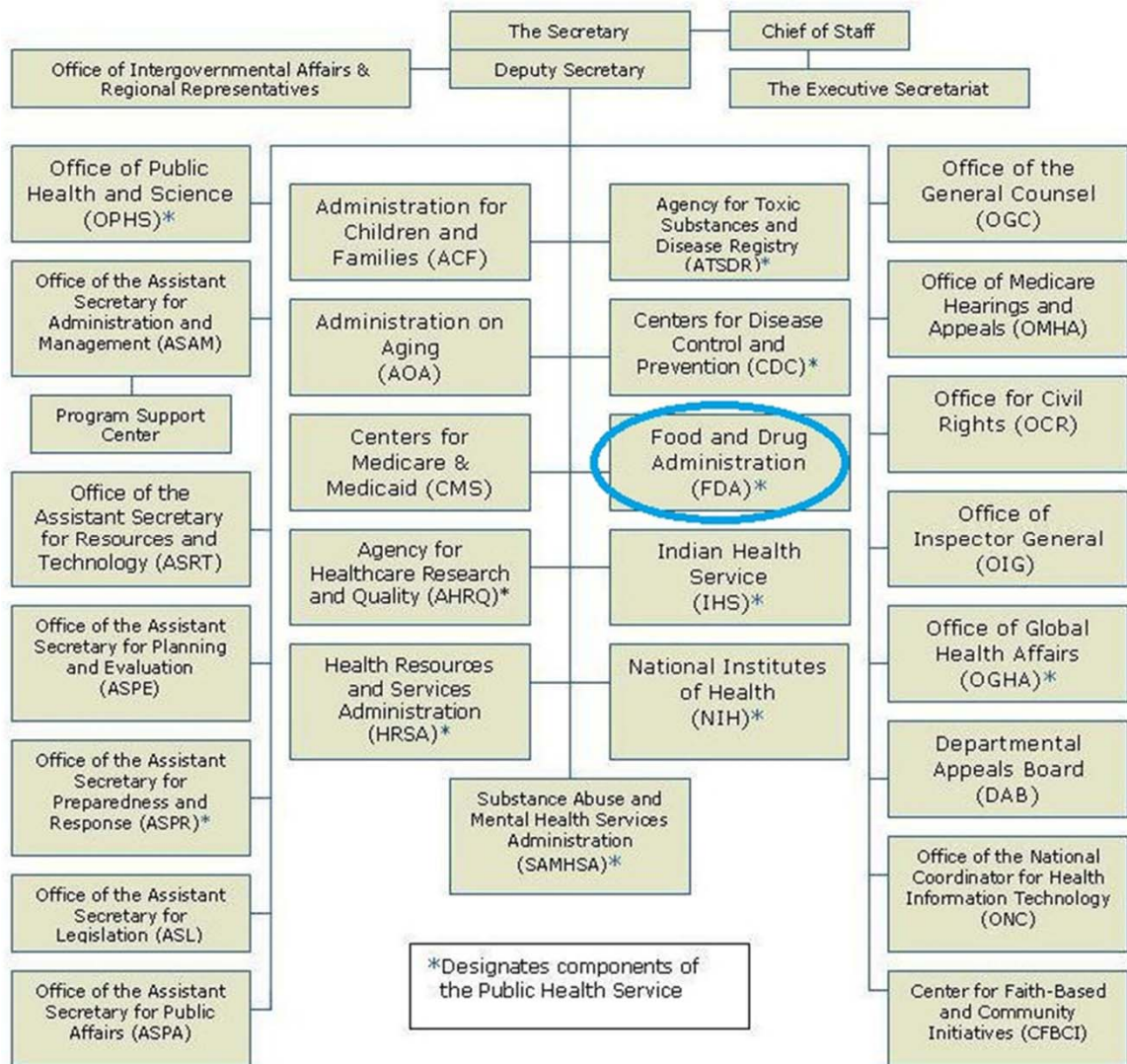
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# FDA's Place in the World



- FDA resides within the US Department of Health and Human Services.
- FDA is a regulatory Agency.
- Employees are both civilian and USPHS.



# Scope of Impact

- FDA-regulated products account for about 20 cents of every dollar of annual spending by U.S. consumers.
- There are over 20,000 prescription drug products approved for marketing.
- FDA has oversight of at least 6,500 different medical device product categories.
- FDA regulates approximately 78% of the US food supply.
- FDA has oversight of more than 90,000 tobacco products.

# FDA CDER Mission



## PROMOTE PUBLIC HEALTH



Ensuring the availability of **safe and effective** drugs



## PROTECT PUBLIC HEALTH



Promoting the **safe use** of marketed drugs



Ensuring the **quality and integrity** of marketed drugs

# Drug Development Process



*De novo* drug discovery and development 10-17 years

<10% overall probability of success

Ashburn and Thor Nature Reviews Drug Discovery, 2004

# Drug Life Cycle

Approval

<p><b>HIGHLIGHTS OF PRESCRIBING INFORMATION</b> These highlights do not include all the information needed to use [DRUG NAME] safely and effectively. See full prescribing information for [DRUG NAME].</p> <p>[DRUG NAME] (nonproprietary name) dosage form, route of administration, essential substance symbol(s)</p> <p>Initial U.S. Approval: [year]</p> <p><b>WARNING: SUBJECT OF WARNING</b> See full prescribing information for complete boxed warning.</p> <ul style="list-style-type: none"> <li>[text]</li> <li>[text]</li> </ul> <p><b>RECENT MAJOR CHANGES</b></p> <p>[section (X.X)] [text]</p> <p>[section (X.X)] [text]</p> <p><b>INDICATIONS AND USAGE</b> [DRUG NAME] is a [name of pharmacologic class] indicated for:</p> <ul style="list-style-type: none"> <li>[text]</li> <li>[text]</li> </ul> <p><b>DOSE AND ADMINISTRATION</b></p> <ul style="list-style-type: none"> <li>[text]</li> <li>[text]</li> </ul> <p><b>DOSE FORMS AND STRENGTHS</b></p> <ul style="list-style-type: none"> <li>[text]</li> </ul>	<p><b>CONTRAINDICATIONS</b></p> <ul style="list-style-type: none"> <li>[text]</li> <li>[text]</li> </ul> <p><b>WARNINGS AND PRECAUTIONS</b></p> <ul style="list-style-type: none"> <li>[text]</li> <li>[text]</li> </ul> <p><b>ADVERSE REACTIONS</b> Most common adverse reactions (incidence) * Pts on [text]</p> <p>For report SUSPECTED ADVERSE REACTIONS, contact [name of manufacturer] at [phone #] or FDA at 1-800-FDA-1088 or <a href="http://www.fda.gov/medwatch">www.fda.gov/medwatch</a>.</p> <p><b>DRUG INTERACTIONS</b></p> <ul style="list-style-type: none"> <li>[text]</li> <li>[text]</li> </ul> <p><b>USE IN SPECIFIC POPULATIONS</b></p> <ul style="list-style-type: none"> <li>[text]</li> <li>[text]</li> </ul> <p>See 17 for PATIENT COUNSELING INFORMATION [and FDA-approved patient labeling (if and applicable)].</p> <p>Revised: [year]</p>
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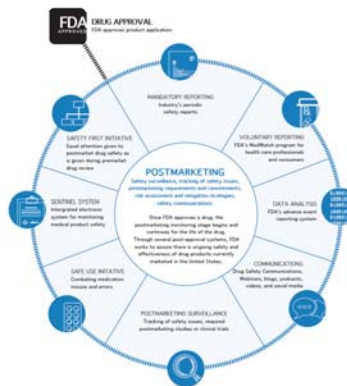
FDA Label



Clinical Trials



Clinical Practice



Post-Marketing Surveillance



# Links to Further References

- Overview of Drug Regulation:
  - <https://www.fda.gov/drugs/development-approval-process-drugs>
- Overview of Device Regulation
  - <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation>
- Questions and Answers on FDA's Adverse Events Reporting System (FAERS):
  - <https://www.fda.gov/drugs/surveillance/fda-adverse-event-reporting-system-faers>



Start of FDA Presentation  
(slides not available)

# End of FDA Presentation



# Cases/HIPAA

- Names
- Address
- DOB
- Phone/Fax #
- Email address
- Social Security #
- Medical Record #



The discussion and materials included in this conference are confidential and privileged pursuant to 26VSA Section 1441-1443. This material is intended for use in improving patient care. It is privileged and strictly confidential and is to be used only for the evaluation and improvement of patient care.



- RECORDING TO BE STOPPED FOR CASE PRESENTATION



# Questions and Discussion from the group....



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# Prep for Next Session

-Prior to each session, if you have specific questions for our faculty expert(s), please let us know and we will pass along ahead of time.

<b>↔ SESSIONS ARE ON FRIDAYS FROM 12:30PM TO 1:30PM ↔</b>		
<b>DATES</b>	<b>SESSION</b>	<b>DIDACTIC TOPICS (in addition to case review)</b>
<b>July 9</b>	TeleECHO Session 1	<b>Managing Opioids Safely and within Vermont Opioid Prescribing Rules</b> (Charles D. MacLean, MD and Amanda Kennedy, PharmD, BCPS)
<b>July 23</b>	TeleECHO Session 2	<b>Overview of the Vermont Prescription Monitoring System (VPMS) for the Dental Team</b> (Hannah Hauser, MSW)
<b>July 30</b>	TeleECHO Session 3	<b>Treatment Modalities for Patients with Chronic Orofacial Pain</b> (Jeffrey Crandall, DDS)
<b>August 13</b>	TeleECHO Session 4	<b>Fundamentals of FDA Regulations of Oral Health Products and U.S. Trends for Opioid and Antibiotic Prescribing in Dentistry</b> (Natalla Chalmers, DDS, MHSc, PhD)
<b>August 27</b>	TeleECHO Session 5	<b>Pain Control to Prevent the Need for Opioid Prescriptions</b> (Raymond Dionne, DDS, PhD)
<b>September 10</b>	TeleECHO Session 6	<b>Dental Management of Patients with Substance Use Disorder</b> (Sue Etminan, DMD, MPH)



# Conclusion

- Slides are posted at [www.vtahec.org](http://www.vtahec.org)
- Volunteers to present cases (this is key to the Project ECHO model)
  - Please submit cases to [Justin.Hurlburt@uvmhealth.org](mailto:Justin.Hurlburt@uvmhealth.org)
- Please complete evaluation survey after each session
- Once your completed evaluation is submitted, CE information will be emailed to you.
- Please contact us with any questions, concerns, or suggestions
  - [Justin.Hurlburt@uvmhealth.org](mailto:Justin.Hurlburt@uvmhealth.org)
  - [Elizabeth.Cote@uvm.edu](mailto:Elizabeth.Cote@uvm.edu)