From: Williams, Paula C.

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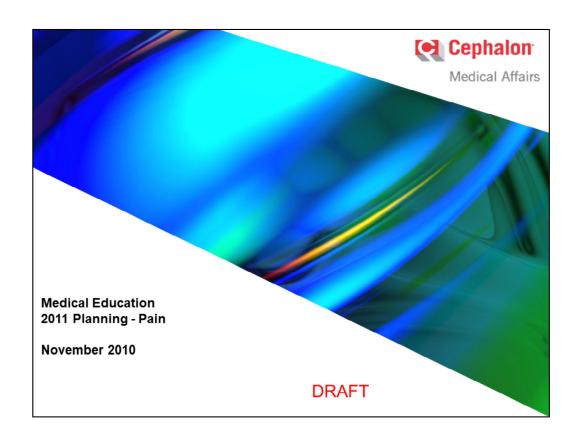
Subject:

Attachments: Med Ed 2011 planning 100710 v3.ppt

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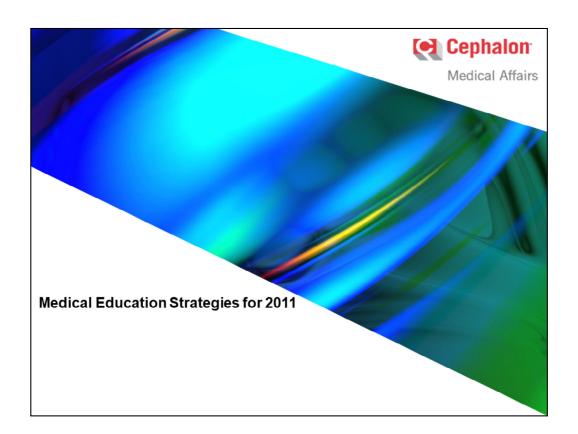
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# **Presentation Overview**

- > Medical Education Strategies for 2011
- > Evidence of Areas of Need for 2011
- Medical Education Activities to Support Areas of Need





# **Medical Education 2011 Strategies**

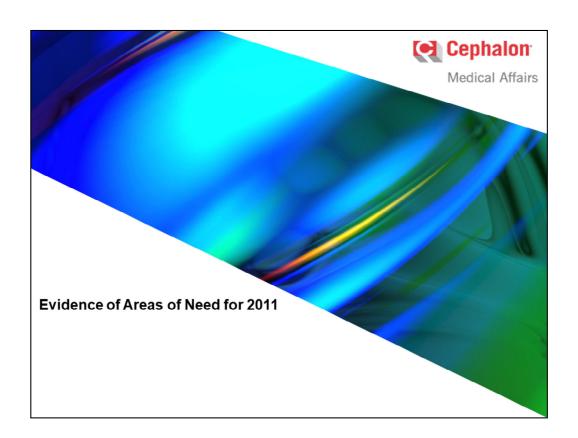
#### Independent

- Increase acceptance of BTP as a medical condition in need of treatment
- Provide education on the appropriate use of opioid medications in the management of chronic pain
- > Provide education on opioid misuse/abuse and the appropriate use of tamper-deterrent (TD) opioids in the management of persistent pain

#### Non-Independent

- Improve awareness/understanding and appreciation of the benefits of Risk Evaluation and Mitigation Strategies (REMS) for opioids
- Improve awareness/understanding and appreciation of the benefits and requirements of the FENTORA and Actiq SECURE Access programs in order to increase acceptance/participation

From 2011 IMP - to be updated when IMP is final



# **Identified Areas of Need**

- 1. Improve BTP Disease State Understanding (including abuse/addiction/diversion/overdose issues)
- 2. General REMS Awareness & Education
- 3. SECURE Access Education & Enrollment



## 1. Disease State Needs

#### Various sources illustrate the need for improved disease state understanding:

- > Breakthrough pain is under-recognized and under-treated.<sup>1</sup>
- > ...there is no generally accepted definition or classification system for cancer BTP. Furthermore, there is no well-validated BTP assessment tool. These deficiencies present a major challenge to the conduct of high quality research as well as to clinical practice.<sup>2</sup>
- Based on the PAINWeek Needs Assessment Survey data, 82% reported that they would like to more accurately assess and diagnose pain through implementation of evidence based tools and techniques.<sup>3</sup>
- Based on the PAINWeek Needs Assessment Survey data, 76% said they need to better understand commonly utilized strategies and treatment guidelines with their patients.<sup>3</sup>
- Owing in part to confusion in terminology, the recognition and assessment of breakthrough pain is oftentimes ad hoc, reflecting a need for education...<sup>4</sup>
- Breakthrough pain terminology remains difficult to grasp across clinician audiences. Approximately half of attendees at 2009 [CME] programs initially failed to correctly define breakthrough pain.<sup>4</sup>

<sup>1</sup>Opioid Therapy in the Management of Chronic Pain: An Integrated Needs Assessment. Interstate Post-graduate Medical Association 2009. pg 58



<sup>2</sup> Haugen DF, et al. Assessment and Classification of Cancer Breakthrough Pain: A Systematic Literature Review. Pain Vol. 149, Issue 3. June 2010. 476-482

<sup>3</sup>PAINWeek 2007 Needs Assessment

<sup>4</sup> Needs Assessment CME Grant Request. Persistent and Breakthrough Pain: Continual, Semi-Structured Assessment for improver Opioid-Based Therapy. February 2010. Grant #5588. p3 & p10

## 1. Disease State Needs (cont'd)

- > Abuse, addiction, diversion, overdose issues related to opioid treatment
  - Public health problem: Opioid abuse and misuse continues to grow<sup>1</sup>
  - Current strategies for intervening with this public health problem are inadequate so REMS will be required<sup>1</sup>
  - Regional / demographic needs
  - Although time consuming, good risk management practice improves patient care and embraces patient communication, documentation, and systematic monitoring<sup>2</sup>
  - ➤ Limited awareness of REMS and the impact on practice<sup>2</sup>



http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM163667.pdf; slide 11

\*\*Opioid Therapy in the Management of Chronic Pain: An Integrated Needs Assessment. Interstate Post-graduate Medical Association 2009. pg 59

# 2. General REMS Awareness & Education Needs

Feedback from RFR faculty/advisors

· Education on opioid REMS should continue as this area evolves

California Academy of Family Physicians Opioid REMS Survey

- Completed by 690 family practice physicians across 9 states
- · Results presented March 16, 2010
- · Recommendations from the report include:
  - Development of an awareness campaign to bring to light the requirements of the pending REMS (majority of respondents were unaware of opioid REMS)

REMS feedback from an internal Market Research study showed there are areas that can be improved upon based on learnings from the launch of the first ROO REMS (FOCUS program)

## 2. General REMS Awareness & Education Needs (cont'd)

#### Fall 2010 Congresses (PainWeek, ASPMN, NCPA)

- PainWeek Ask The Experts Sessions (Drs. Passik, Brennan, Kaper & Narayana)
  - Surveys showed a mix of positive and negative results when asked about the impact of opioid REMS
  - 77% of respondents (n=18) said there was not enough information available on REMS
    - When asked what are the most important aspects to know about REMS, the top 3 answers were:
      - Practical advice
      - How REMS will affect my ability to prescribe
      - · How REMS will affect my patients
- Key take-aways from all meetings
  - > 130 attendees signed up for more information
  - Received some large requests for materials & for in-service talks
  - Much of the dialogue centered on explaining REMS components and potential impact to each stakeholder
    - Nurses recognized that much of the patient interaction will fall on them
    - Pharmacists were concerned they will be left out of the REMS communications and were looking for materials to talk to particular of the REMS communications and were looking for materials to talk to particular of the REMS communications and were looking for materials to talk to particular of the REMS communications and were looking for materials to talk to particular of the REMS communications and were looking for materials to talk to particular of the REMS communications and were looking for materials to talk to particular of the REMS communications and were looking for materials to talk to particular of the REMS communications and were looking for materials to talk to particular of the REMS communications and were looking for materials to talk to particular of the REMS communications and were looking for materials to talk to particular of the REMS communications and were looking for materials to talk to particular of the REMS communications and were looking for materials to talk to particular of the REMS communications and were looking for materials to talk to particular of the REMS communications and were looking for materials to talk to particular of the REMS communications and the REMS communications and the REMS communications and the REMS communications are looking to the REMS communications and the REMS communications are looking to the REMS communications and the REMS communications are looking to the REMS communications and the REMS communications are looking to the REMS communications and the REMS communications are looking to the REMS communications and the REMS communications are looking to the REMS communications and the REMS communications are looking to the REMS communications and the REMS communications are looking to the REMS looking for materials to talk to patients about REMS

### 3. SECURE Access Education & Enrollment Needs

As of April 2010\*, there were ~20,000 writers of *FENTORA*, Actiq, and/or OTFC

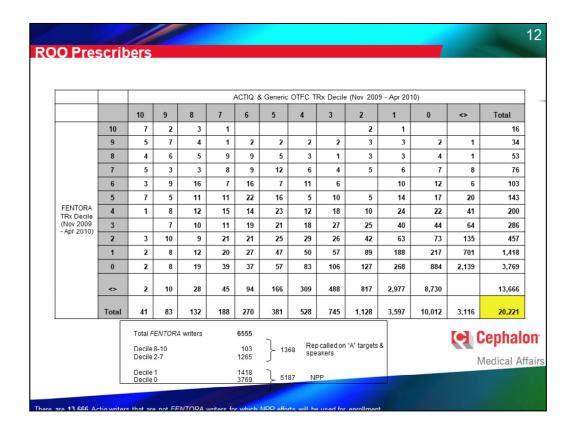
> A broad reach is needed to ensure that key stakeholders are educated and enrolled so there is no interruption to patient care

Evidence exists that physicians would be in favor of pain management CME credits including REMS education

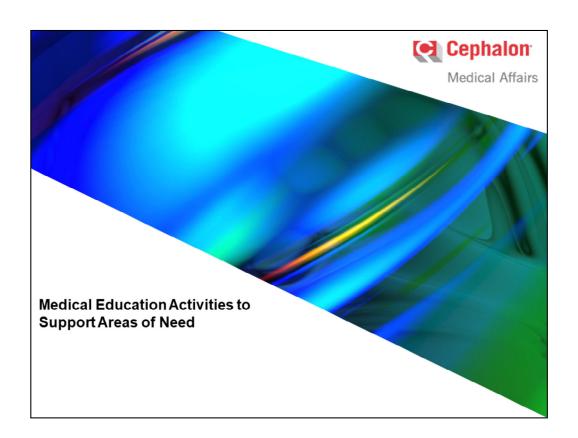
- > Based on a California Academy of Family Physicians Opioid REMS Survey
  - Completed by 690 family practice physicians across 9 states
  - · Results presented March 16, 2010



\*writers that prescribed during the time period April 2008 – April 2010



Decile 0 = not written in current 6 months but wrote in prior 18 months = wrote but not in recent 24 months



## **Activities Based on Areas of Need - Summary**

Based on the identified needs, four areas of activities for the Pain Medical Education team to focus on in 2011 are:

- 1. CME\*- Pain education to improve disease state understanding
- Raise awareness and educate on general REMS with Ready For REMS activities
- CME\*- SECURE Access: roll-out of education and enrollment (based on necessary accreditation guidance/approval)
- 4. Non CME SECURE Access: roll-out of education and enrollment



Medical Affairs

\*Support provided by Cephalon for 3<sup>rd</sup> party independent education

## 1. CME - Pain Education

#### > Education:

 Learning objectives include defining chronic pain, defining/recognizing BTP, differentiating BTP episodes from uncontrolled persistent pain, properly assessing and treating BTP, including appropriate patient selection, risk assessment, patient function, treatment goals, etc.

> Audience: HCPs\*

> Timing: ongoing throughout 2011

> Cost: Budget = \$1,750,000

> Metrics: Outcomes furnished by IME providers



Medical Affairs

\* HCPs include prescribers, PAs, nurses, NPs, and pharmacists

## 2. REMS education - Ready For REMS 2011

#### > Objective:

- Medical Education to continue Ready For REMS (RFR) program to raise REMS awareness, provide REMS background and education, and support opioid REMS
- RFR will have an online presence only

> Audience: HCPs\*

> Timing: Ongoing throughout 2011

> Cost: \$650,000

> Metrics: Website metrics provided by AS&K, other metrics provided by Quantia and/or Medscape or other outreach partner



Medical Affairs

\* HCPs include prescribers, PAs, nurses, NPs, and pharmacists

## 2. REMS education - Ready For REMS 2011

RFR activities will continue in 2011 as the opioid REMS landscape continues to evolve

#### Strategic Objectives:

- To continue to raise awareness and prepare healthcare providers for the FDA-mandated REMS for opioids
- To provide practical tips for incorporating REMS into every day practice for physicians, nurses, and pharmacists

#### **Target Audience**

Prescribers, nurses, NPs/PAs, Pharmacists

#### Maintain online presence only for 2011

- Continue to support online portal with information and updates on REMS for opioids (www.readyforrems.com)
- Improve outreach to ensure content reaches appropriate participants/stakeholders including prescribers, nurses, NPs/PAs, pharmacists
  - Explore journal advertising and online media outreach & Medscape partnership
  - **Explore Pharmacy Schools Mailer**
  - **Professional Societies Mailer**
- Maintain presence at scientific meetings via room drops & sponsorships

  Make all RFR materials available to all functional areas for their use

## 3. CME\* - SECURE Access roll-out

## > Education:

 Learning objectives include safe use of opioids, appropriate patient selection, opioid tolerance, and proper dosing; plus the opportunity to enroll into SECURE Access

> Audience: HCPs\*\*

> Timing: January/February 2011

> Cost: \$1.1m

> Metrics: Outcomes furnished by IME providers



<sup>\*</sup> Based on necessary accreditation guidance/approval

<sup>\*\*</sup> HCPs include prescribers, PAs, nurses, NPs, and pharmacists

## 4. Non-CME - SECURE Access roll-out

- > Objectives:
  - Educate on BTP, need to treat, ROOs, FENTORA/Actiq, overview of SECURE Access, enrollment in SECURE Access
- > Audience: ROO writers, nurses, NPs/PAs, pharmacists
- > Cost: \$1.5m
- Metrics: Outcomes furnished by Medical Education Department

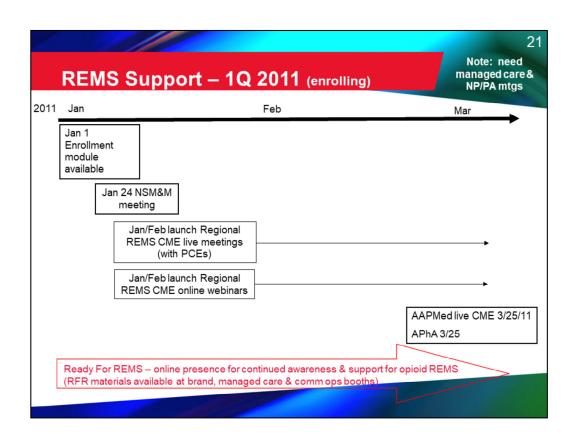


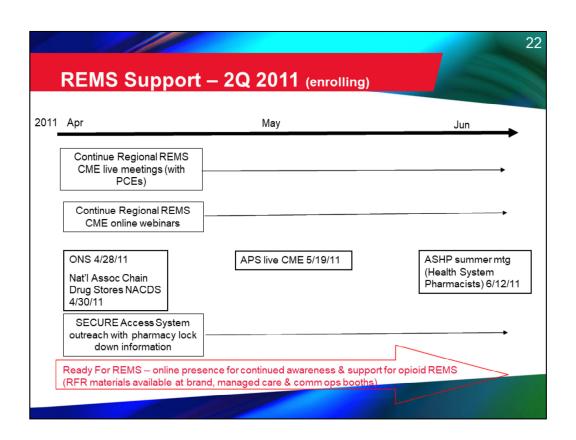
## 4. Non-CME - SECURE Access roll-out (cont'd)

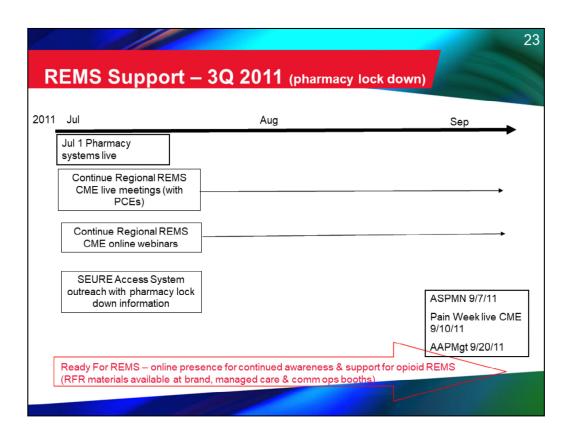
#### Program specifics:

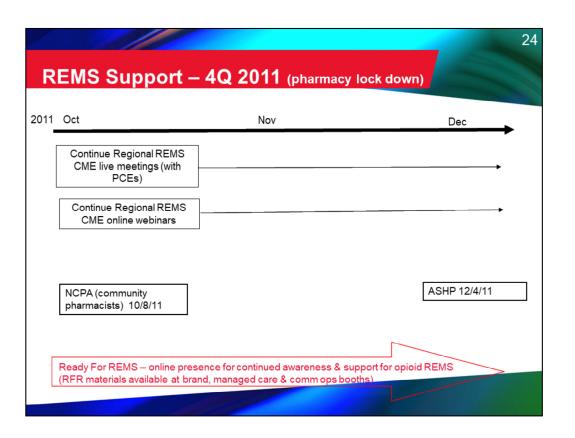
- > Series of ~15 live regional education meetings (near Pain Care Centers of Excellence) to start in January/February and run through 2011
  - Safe use of opioids, ROOs, appropriate patient selection, opioid tolerance, overview of SECURE Access
  - Opportunity to enroll in SECURE Access
  - ~50-100 attendees at each
- > Series of ~15 online education webinars (mirroring live meetings) to run through 2011
- > Live meetings at: AAPM, APS, PainWeek
  - 90 minute symposium with meal
    - Safe use of opioids, ROOs, appropriate patient selection, opioid tolerance, overview of SECURE Access
    - Meet and greet KOL, Cephalon Medical Affairs
    - Opportunity to enroll in SECURE Access
- > Pulsed reminders to participants of system lock-down
- Medical Affairs to sponsor a hospitality suite for enrollment throughout the meeting











## 25 **Budget\*** 2011 Medical Education Budget Summary - Pain Initiative **Estimate** \$1,750,000 CME - Pain \$3,291,700 **REMS** RFR \$645,200 CME REMS \$1,100,000 SECURE Access Roll-out \$1,546,500 \$5,041,700 Total **Cephalon** Medical Affairs \*approved October 2010