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To: Peletsky, Lisa
Subject: Fentora Model Call
Attachments: FENTORA Model Sales Call Behavior FINAL.pdf

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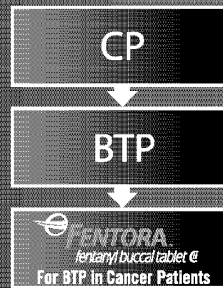
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Model Sales Call Behavior

For All
Health Care
Providers

OBJECTIVE

This document provides revised and further guidance on expected behavior to conduct an effective sales call that meets business, regulatory and other compliance requirements. This version of the model sales call supersedes any previous versions and all other versions must be destroyed.



Chronic Pain (CP), BTP, and FENTORA have unique challenges and promotional messages; however, they are all interconnected and you should make these connections to properly promote the product. It is important to note that all discussions must tie back to breakthrough pain in opioid-tolerant patients with cancer.

IMPORTANT

Chronic pain has two distinct components: persistent pain and breakthrough pain. BTP is under-diagnosed and often misdiagnosed. In addition, physicians may not fully understand or properly screen for BTP. Therefore, it is critical that we are able to appropriately educate physicians about patient recognition (e.g. presentation, co-morbidities, and characteristics) and consequences associated with not properly treating BTP. Any discussion of CP & BTP must be followed by a discussion pertaining to BTP in opioid-tolerant patients with cancer.

Depending on the length of time that you have with the physician, you may not be able to cover each promotional message surrounding Chronic Pain, BTP, and FENTORA on every call. You may have to share these key messages over several calls with the same physician. This is an appropriate approach as long as you tie all discussions back to the disease state for which FENTORA is indicated (BTP in opioid-tolerant patients with cancer).

Not every call can be scripted and this document is not intended to be used in that manner. Rather, this document sets out the general parameters regarding what is appropriate behavior when calling on a physician. You should remain within the boundaries set forth in this document and if you feel uncertain as to how to handle a specific situation, you should contact your Area Manager.

Although each sales call will vary, certain basic principles apply to all calls including the following do's and don'ts:

DO's

- State the indication of FENTORA and Communicate the 3 objectives of the Risk Minimization Action Plan (RiskMAP) or the SECURE Program (Solutions through Education, Communication and Understanding Risk minimization Excellence) on every call.
 - Ensure that patients and Health Care Providers understand that FENTORA should only be used by opioid tolerant patients with cancer
 - Minimize the potential for misuse, abuse, and diversion of FENTORA
 - Minimize unintended or accidental exposure to FENTORA
- Attempt to communicate the key promotional messages on every call:
 - FENTORA matches the sudden onset of BTP in some patients with cancer
 - Early Onset of Relief
 - 15 minutes in initial study (first time point measured)
 - 10 minutes in subsequent study
 - Readily absorbed across the buccal mucosa
 - Early and extensive systemic exposure
 - Employs unique OraVescent Technology
 - Convenient, Discreet, Sugar-Free Tablet, Acetaminophen-Free
- Discussion of the efficacy of FENTORA must also include a fair balanced discussion regarding the safety profile of the product
- If the Health Care Provider brings up an off-label use when responding to your question:
 - Submit a MIRF for unsolicited questions.
 - Refocus the discussion on BTP in patients with cancer.
 - Discuss the attributes and clinical benefits of FENTORA within BTP in opioid-tolerant patients with cancer
- Discussions of WLF papers must be in response to an unsolicited question and limited to the following information:
 - Title of the article
 - Where the article was published
 - Date of publication
 - Study design (e.g. double-blinded, placebo controlled)
 - Number of patients (but not patient type)

DON'Ts

- Never promote FENTORA for a use outside its labeled indication.
- Never reference other physicians and their non-indicated use of FENTORA.
- Never probe a physician on the use of FENTORA for an off-label use.
- Never use promotional materials that are not currently PDRC approved for use.
- Never proactively discuss WLF reprints.
- Never probe a Health Care Provider on any of the topics discussed in the WLF reprint.
- Never discuss the following information contained within the WLF reprint:
 - Results
 - Dosing
 - Administration
 - Efficacy or Safety

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OPEN

- You may open the call with questions from Group 1 and/or 2 below (Chronic Pain, BTP, FENTORA), however, you may only ask 2 to 3 questions collectively from Group 1.
- In the event that an HCP responds with a comment or question outside of the labeled indication, you must then state the approved indication for the product. At this point you can only ask questions from Group 2 that are based specifically on our approved indication (breakthrough pain in opioid-tolerant patients with cancer) and/or move to the body of the sales call.

CHRONIC PAIN EXAMPLES

- How do you recognize and/or diagnose Chronic Pain?
- What do you think are the potential consequences of Chronic Pain, and/or failure to treat Chronic Pain?
- Are you aware that Chronic Pain has two components: persistent pain and BTP?
- How do you differentiate between Persistent Pain & BTP?
- Which Chronic Pain assessment tools do you utilize?

1

BTP EXAMPLES

- How do you recognize and/or diagnose BTP?
- What do you think are the potential consequences of BTP, and/or failure to properly treat BTP?
- Approximately 70% of patients with Chronic Pain suffer from BTP. These patients often describe BTP as striking without warning, escalating to maximum intensity within minutes, and occurring on average 2-4 times per day.
- Are any of your Chronic Pain patients reporting uncontrolled BTP episodes?
- Are you aware that BTP has been shown to predict poor medical outcomes, increase morbidity, and decreased functioning?
- How do your patients describe their BTP episodes? What words do they use?
- What characteristics would you find essential in a BTP medication that current therapies are lacking?

1

FENTORA EXAMPLES

- What type of feedback are you hearing from patients you have put on FENTORA?
- How do you determine which patients are candidates for FENTORA?
- In your opinion, what are the main attributes of FENTORA?
- Where does FENTORA fit into your practice?

1

HCP Response for Chronic Pain Examples

When asked the above questions, possible answers by Health Care Providers could include:

- Consequences of not properly treating Chronic Pain
- Challenges associated with treating Chronic Pain
- Use of opioids for Chronic Pain

HCP Response for BTP Examples

When asked the above questions, possible answers by Health Care Providers could include:

- Consequences of not properly treating BTP
- Challenges associated with treating BTP
- Use of opioids for BTP
- Use of FENTORA for BTP

HCP Response for FENTORA Examples

When asked the above questions, possible answers by Health Care Providers could include:

- Attributes of FENTORA
- Feedback from patients on FENTORA
- Results of FENTORA for treatment of BTP in other disease states
- Experience with various methods currently used to treat breakthrough cancer pain

Please Note

When a Health Care Provider responds with an off-label question:

- Submit a MIRF
- Transition back to relevant information surrounding FENTORA, BTP, and Chronic Pain

FENTORA

You can use these probes/examples to open a call; however, if you opened with any of the examples from Group 1 above, you **must** continue the dialogue with the following examples:

- 51-89% of cancer patients with controlled persistent pain experience BTP. These patients often describe BTP as striking without warning, escalates to maximum intensity in as little as three minutes, the majority of episodes last 120 minutes or less, and the median number of episodes is 4-7 times per day.
- In your cancer patients how do you determine what is a clinically significant improvement in the pain intensity of a BTP episode?
- In your cancer patients do you differentiate your treatment approach based on pain pathophysiology?
- How do you titrate your cancer patients to an effective FENTORA dose? Do you base this on the around-the-clock medication and dose?
- What current medications do you primarily use to treat BTP episodes in your cancer patients and are you satisfied with the results?
- In your cancer patients how do you define pain relief of a BTP episode?
- In your cancer patients how do you define a success in regards to BTP management?
- In your cancer patients which strength of FENTORA do you most commonly prescribe?
- In your cancer patients what do you find is the most commonly reported benefit of FENTORA compared to their previous BTP medication?

Key

- Group 1
- Group 2

2

BODY

Work on creating a paradigm shift in the thinking of the physician to be more sensitive/open to identifying and treating patients with BTP in patients with cancer; reinforce clinical benefits of FENTORA within the indication.

- The sales specialist informs the physician of the approved indications for FENTORA.
- Discuss benefits of OraVescent technology, fentanyl characteristics, PK profile, safety profile, side effects, sugar-free, discreet therapy, etc. Present balance in your presentation.
- Use current approved promotional tools (e.g., Core Visual Aid or clinical reprints) for proof sources.
- Ask the following types of questions about their patients with BTP in cancer: Recognition of symptoms, Treatment options, and Experience with Rapid Onset Opioid (ROO).
- Patient/practice success stories with FENTORA.
- Submit MIRFs for unsolicited questions initiated by the physician that are off-label.
- Look for buying signals and opportunities to drive an increase in the appropriate prescriptions of your prescriber HCP.

CLOSE

Ask more closed ended questions where the answer is more likely to be "yes".

- Would you feel comfortable using the Chronic Pain assessment tool to help diagnose persistent pain and BTP?
- Based on our discussion, do you have Chronic Pain patients with cancer experiencing BTP?
- FENTORA optimizes onset of pain relief for BTP in opioid tolerant patients with cancer. Will you continue to use FENTORA in your practice?

Always ask the physician if they need additional education or support materials.

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