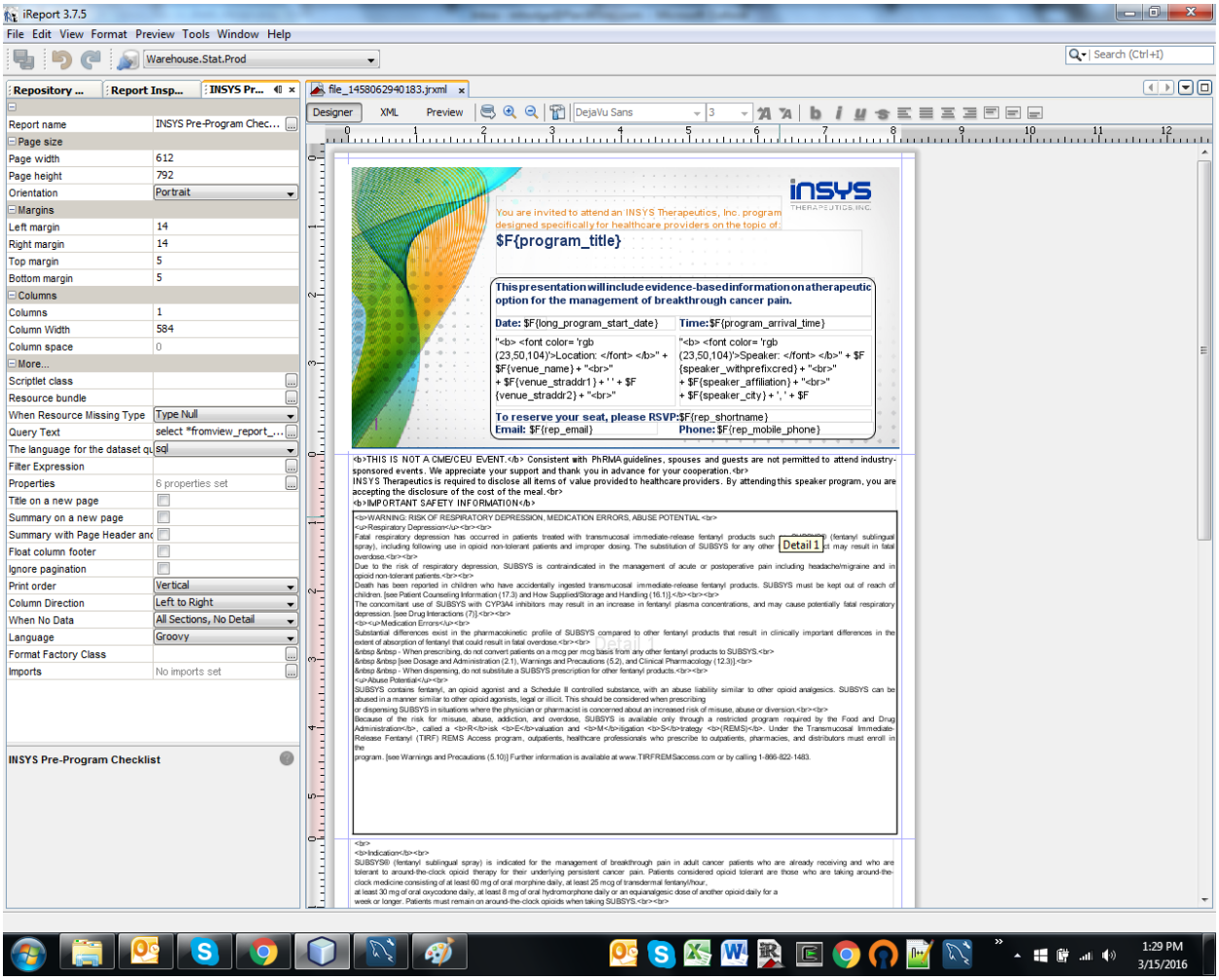
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THERAPEUTICS INC.
You are invited to attend an INSYS Therapeutics, Inc. program
designed specifically for healthcare providers on the topic of:
$F{program_title}
This presentation will include evidence-based information on a therapeutic
option for the management of breakthrough cancer pain.
Date: $F{long_program_start_date}
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To reserve your seat, please RSVP:$F{rep_shortname}
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Phone: $F{rep_mobile_phone}
THIS IS NOT A CME/CEU EVENT. Consistent with PhRMA guidelines, spouses and guests are not permitted to attend industry-sponsored events. We appreciate your support and thank you in advance for your cooperation.
INSYS Therapeutics is required to disclose all items of value provided to healthcare providers. By attending this speaker program, you are accepting the disclosure of the cost of the meal.
IMPORTANT SAFETY INFORMATION
WARNING: RISK OF RESPIRATORY DEPRESSION, MEDICATION ERRORS, ABUSE POTENTIAL
<u>Respiratory Depression</u>

Fatal respiratory depression has occurred in patients treated with transmucosal immediate-release fentanyl products such as SUBSYS® (fentanyl sublingual spray), including following use in opioid non-tolerant patients and improper dosing. The substitution of SUBSYS for any other Detail 1 ct may result in fatal overdose.

Due to the risk of respiratory depression, SUBSYS is contraindicated in the management of acute or postoperative pain including headache/migraine and in opioid non-tolerant patients.

Death has been reported in children who have accidentally ingested transmucosal immediate-release fentanyl products. SUBSYS must be kept out of reach of children. [see Patient Counseling Information (17.3) and How Supplied/Storage and Handling (16.1)].

The concomitant use of SUBSYS with CYP3A4 inhibitors may result in an increase in fentanyl plasma concentrations, and may cause potentially fatal respiratory depression. [see Drug Interactions (7)].

<u>Medication Errors</u>
Substantial differences exist in the pharmacokinetic profile of SUBSYS compared to other fentanyl products that result in clinically important differences in the extent of absorption of fentanyl that could result in fatal overdose.

    - When prescribing, do not convert patients on a mcg per mcg basis from any other fentanyl products to SUBSYS.
    [see Dosage and Administration (2.1), Warnings and Precautions (5.2), and Clinical Pharmacology (12.3)].
    - When dispensing, do not substitute a SUBSYS prescription for other fentanyl products.

<u>Abuse Potential</u>
SUBSYS contains fentanyl, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. SUBSYS can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing
or dispensing SUBSYS in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion.

Because of the risk for misuse, abuse, addiction, and overdose, SUBSYS is available only through a restricted program required by the Food and Drug Administration, called a Risk Evaluation and Mitigation Strategy: REMS. Under the Transmucosal Immediate-Release Fentanyl (TIRF) REMS Access program, outpatients, healthcare professionals who prescribe to outpatients, pharmacies, and distributors must enroll in the
program. [see Warnings and Precautions (5.10)] Further information is available at www.TIRFREMSaccess.com or by calling 1-866-822-1483.

Indication
SUBSYS® (fentanyl sublingual spray) is indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour,
at least 30 mg oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a
week or longer. Patients must remain on around-the-clock opioids when taking SUBSYS.

1:29 PM
3/15/2016

You are invited to attend an INSYS Therapeutics, Inc. program designed specifically for healthcare providers on the topic of:

Managing Chronic Pain in Cancer Survivors, Benefit-Risk of Long-Term Opioid Therapy

This presentation will include evidence-based information on a therapeutic option for the management of breakthrough cancer pain.

Date: February 10, 2015

Time: 12:00 PM

Location: Ichiban
2167 South McKenzie Street
Foley, AL 36535

Speaker: Dr. Rony Lee, MD
Gulf Coast Occupational Sports
Foley, AL

To reserve your seat, please RSVP: Natalie Perhacs
Email: nperhacs@insysrx.com **Phone:** 205-746-2441

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IMPORTANT SAFETY INFORMATION

WARNING: RISK OF RESPIRATORY DEPRESSION, MEDICATION ERRORS, ABUSE POTENTIAL

Respiratory Depression

Fatal respiratory depression has occurred in patients treated with transmucosal immediate-release fentanyl products such as SUBSYS® (fentanyl sublingual spray), including following use in opioid non-tolerant patients and improper dosing. The substitution of SUBSYS for any other fentanyl product may result in fatal overdose.

Due to the risk of respiratory depression, SUBSYS is contraindicated in the management of acute or postoperative pain including headache/migraine and in opioid non-tolerant patients.

Death has been reported in children who have accidentally ingested transmucosal immediate-release fentanyl products. SUBSYS must be kept out of reach of children. [see Patient Counseling Information (17.3) and How Supplied/Storage and Handling (16.1)].

The concomitant use of SUBSYS with CYP3A4 inhibitors may result in an increase in fentanyl plasma concentrations, and may cause potentially fatal respiratory depression. [see Drug Interactions (7)].

Medication Errors

Substantial differences exist in the pharmacokinetic profile of SUBSYS compared to other fentanyl products that result in clinically important differences in the extent of absorption of fentanyl that could result in fatal overdose.

- **When prescribing, do not convert patients on a mcg per mcg basis from any other fentanyl products to SUBSYS. [see Dosage and Administration (2.1), Warnings and Precautions (5.2), and Clinical Pharmacology (12.3)].**
- **When dispensing, do not substitute a SUBSYS prescription for other fentanyl products.**

Abuse Potential

SUBSYS contains fentanyl, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. SUBSYS can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing SUBSYS in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion.

Because of the risk for misuse, abuse, addiction, and overdose, SUBSYS is available only through a restricted program required by the Food and Drug Administration, called a **R**isk **E**valuation and **M**itigation **S**trategy **(REMS)**. Under the Transmucosal Immediate-Release Fentanyl (TIRF) REMS Access program, outpatients, healthcare professionals who prescribe to outpatients, pharmacies, and distributors must enroll in the program. [see Warnings and Precautions (5.10)] Further information is available at www.TIRFREMSaccess.com or by calling 1-866-822-1483.

Please see full Prescribing Information, including Boxed Warning and Medication Guide for SUBSYS.

Indication
SUBSYS® (fentanyl sublingual spray) is indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking SUBSYS.

This product **must not** be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, SUBSYS is contraindicated in the management of acute or postoperative pain.
SUBSYS is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

Limitations of Use
As part of the Transmucosal Immediate-Release Fentanyl (TIRF) REMS ACCESS Program, SUBSYS may be dispensed only to outpatients enrolled in the program. For inpatient administration (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use) of SUBSYS, patient enrollment is not required.

IMPORTANT SAFETY INFORMATION
Contraindications

- SUBSYS is contraindicated in opioid non-tolerant patients
- SUBSYS is contraindicated in the management of acute or postoperative pain including headache/migraine. Life-threatening respiratory depression and death could occur at any dose in opioid non-tolerant patients
- SUBSYS is contraindicated in patients with known intolerance or hypersensitivity to any of its components or the drug fentanyl. Anaphylaxis and hypersensitivity have been reported in association with the use of other oral transmucosal fentanyl products

Warnings and Precautions

- Clinically significant respiratory depression can occur. Respiratory depression is more likely to occur in patients with underlying respiratory disorders and elderly or debilitated patients, usually following large initial doses in opioid non-tolerant patients, or when opioids are given in conjunction with other drugs that depress respiration
- Monitor patients with Grade 1 mucositis closely for signs of respiratory and central nervous system depression particularly during initiation of therapy with SUBSYS. The use of SUBSYS should be avoided in patients with Grade 2 and more severe mucositis unless the benefits are expected to outweigh the risk of respiratory depression
- **SUBSYS is not bioequivalent with other fentanyl products. Do not convert patients on a mcg per mcg basis from other fentanyl products. DO NOT substitute a SUBSYS prescription for any other fentanyl product, a substitution may result in a fatal overdose**
- Patients and caregivers must be instructed that SUBSYS contains a medicine in an amount which can be fatal to a child and thus must keep used and unused dosage units out of the reach of children.
- The concomitant use of SUBSYS with other CNS depressants, including other opioids, sedatives or hypnotics, general anesthetics, phenothiazines, tranquilizers, skeletal muscle relaxants, sedating antihistamines, and alcoholic beverages may produce increased depressant effects (e.g., respiratory depression, hypotension, and profound sedation). Concomitant use with strong and moderate inhibitors of CYP450 3A4 isoform (e.g., erythromycin, ketoconazole, and certain protease inhibitors) may increase fentanyl levels, resulting in increased depressant effects. Patients on concomitant CNS depressants must be monitored for a change in opioid effects. Consideration should be given to adjusting the dose of SUBSYS if warranted
- Patients taking SUBSYS must be warned that opioid analgesics impair the mental and/or physical ability required for the performance of potentially dangerous tasks (e.g., driving a car or operating machinery). Warn patients taking SUBSYS of these dangers and counsel them accordingly
- Because potent opioids can cause respiratory depression, titrate SUBSYS with caution in patients with chronic obstructive pulmonary disease or preexisting medical conditions predisposing them to respiratory depression. In such patients, even normal therapeutic doses of SUBSYS may further decrease respiratory drive to the point of respiratory failure
- Administer SUBSYS with extreme caution in patients who may be particularly susceptible to the intracranial effects of CO2 retention such as those with evidence of increased intracranial pressure or impaired consciousness
- Use SUBSYS with caution in patients with bradyarrhythmias
- SUBSYS is not recommended for use in patients who have received MAO inhibitors within 14 days because severe and unpredictable potentiation by MAO inhibitors has been reported with opioid analgesics

Drug Interactions

- Monitor patients for opioid toxicity who begin therapy with, or increase the dose of, inhibitors of CYP450 3A4, or stop therapy with, or decrease the dose of, inducers of CYP450 3A4

Use in Specific Populations

- Safety and efficacy in pediatric patients below the age of 18 years have not been established

Adverse Reactions

- The most serious adverse reactions associated with all opioids including SUBSYS are respiratory depression (potentially leading to apnea or respiratory arrest), circulatory depression, hypotension, and shock. Follow all patients for symptoms of respiratory depression
- The most common adverse events during titration (frequency 5%): nausea, vomiting, constipation, somnolence, and dizziness
- The most common adverse events subsequent to titration (frequency 5%): vomiting, nausea, constipation, asthenia, dyspnea, and anxiety
- The most common adverse reaction leading to discontinuation of SUBSYS was nausea. There were also adverse reactions of abdominal distension, anorexia, confusional state, disorientation, somnolence, and constipation

Please see full Prescribing Information, including Boxed Warning and Medication Guide for SUBSYS.

INSYS THERAPEUTICS, INC.