

Appendix 1

Text of Computerized Survey (text in red is not visible to respondent)

You are invited to participate in a survey collecting information and opinions about prescribing and dispensing abuse deterrent formulation opioid analgesics. Researchers at the University of Kentucky Colleges of Pharmacy and Public Health are conducting this study on behalf of the U.S. Food and Drug Administration.

We are asking you to participate in this survey because you are a licensed pharmacist with the ability to dispense controlled substances in <the appropriate state will be selected: North Carolina or Florida>. Your participation in this survey is voluntary, and it will take approximately 6 minutes to complete. The survey asks about stocking and dispensing abuse deterrent formulation opioid analgesics in your pharmacy. We will use the information generated from this research to assist in our understanding of how these medications are being used in practice.

Your response to the survey is anonymous. The research team will not know who did, or did not, respond to the survey and will not attempt to trace responses back to individuals. We do not know of any risks associated with disclosure of your opinions about prescribing and dispensing abuse deterrent formulations of opioid analgesics. Your information will be kept secure to the extent permitted by law. You may receive two additional email invitations to participate in this survey over the next two weeks. If you have already responded or elect not to respond to the survey, please ignore these additional emails.

Taking part in this research is completely voluntary. If you choose not to participate, there will be no penalty to you. You are free to skip any question that you do not want to answer, and you can discontinue the survey at any time. Although you will not personally benefit from completing the survey, the information that you provide may help us understand how to use abuse deterrent formulations more effectively.

The University of Kentucky Medical Institutional Review Board has reviewed this study. If you have questions about this study, please call Patricia Freeman at 859-323-1381 or Svetla Slavova at 859-323-7873. If you have any questions about your rights as a volunteer in this research, please call the staff in the Office of Research Integrity at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428.

By clicking the "Next" button, you have given your consent to participate. Click the "Next" button (below) to start the survey. Thank you for your time, and we appreciate your consideration in completing this survey.

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OMB Control No. 0910-0847

Expiration Date: 12/31/2022

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0847 and the expiration date is 12/31/2022. The time required to complete this information collection is estimated to average 6 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden, to PRASStaff@fda.hhs.gov.

This study is being conducted on behalf of the U.S. Food and Drug Administration by researchers at the University of Kentucky Colleges of Pharmacy and Public Health.

Eligibility Question

Do you fill and dispense opioid analgesic prescriptions in your practice?

No [0]

Yes [1]

If the respondent answer is [0], stop:

Thank you for your willingness to participate. This survey focuses on the dispensing of opioid analgesic prescriptions. We look forward to your participation in future surveys.

Section 1. Questions about your perception of abuse deterrent formulation opioids.

One of the ways that the U.S. Food and Drug Administration (FDA) has tried to address the opioid epidemic is by approving opioid analgesic products that are designed to be harder to manipulate and abuse. These so-called “abuse deterrent formulations” (e.g., OxyContin®, Embeda®, etc.) are intended to make certain types of abuse, such as crushing a tablet to snort or dissolving a capsule to inject, more difficult or less rewarding.

1. Considering your experience dispensing opioid analgesics, how would you rate your familiarity with abuse deterrent formulation opioids?

Choices presented are:

- 1 Not familiar at all
- 2 Somewhat familiar
- 3 Familiar
- 4 Very familiar
- 5 Unsure

2. Please indicate the extent to which you agree or disagree with the following statements:

2a. In my professional opinion, to **GAIN** FDA approval, all new opioid analgesics should meet FDA standards as abuse deterrent formulations.

Choices presented are:

- 1 Strongly disagree
- 2 Disagree
- 3 Agree
- 4 Strongly agree
- 5 Unsure

2b. In my profession opinion, to **MAINTAIN** FDA approval, all existing opioid analgesics should meet FDA standards as abuse deterrent formulations.

Choices presented are:

- 1 Strongly disagree
- 2 Disagree
- 3 Agree
- 4 Strongly agree
- 5 Unsure

2c. Abuse deterrent opioid analgesics are effective at mitigating opioid misuse and abuse.

Choices presented are:

- 1 Strongly disagree
- 2 Disagree
- 3 Agree
- 4 Strongly agree
- 5 Unsure

3. When making dispensing decisions regarding opioid analgesic prescriptions, do you consider whether or not the opioid is an abuse deterrent formulation?

0 No

1 Yes

If the answer to question 3 is [0], the respondent will be asked: Please describe why you do not make this consideration.

If the answer to question 3 is [1], the respondent will be asked: Please describe why you make this consideration.

Section 2. Questions about your experience dispensing abuse deterrent formulation opioid analgesics.

4. Which of the following best describes your dispensing experience with Hysingla ER (hydrocodone bitartrate extended-release)?

Choices presented are:

1 Not in stock, Never dispensed

2 In stock, Never dispensed

3 Rarely (i.e., a few times a year)

4 Occasionally (i.e., monthly)

5 Frequently (i.e., daily - weekly)

If the answer to question 4 is [2-5], the respondent will go to question 5

If the answer to question 4 is [1], the respondent will be asked this follow-up:

Please indicate the primary reason(s) why they are not stocked in your pharmacy.

Choices presented are:

1 Too few prescriptions presented to pharmacy

2 Inventory costs are too great

3 Lack of third-party coverage makes them unaffordable for patients

4 Time and resources involved in securing third-party payment approval (e.g., prior authorization)

5 Other [please describe]

5. Which of the following best describes your dispensing experience with OxyContin (oxycodone hydrochloride extended-release)?

Choices presented are:

1 Not in stock, Never dispensed

2 In stock, Never dispensed

3 Rarely (i.e., a few times a year)

4 Occasionally (i.e., monthly)

5 Frequently (i.e., daily - weekly)

If the answer to question 5 is [2-5], the respondent will go to question 6

If the answer to question 5 is [1], the respondent will be asked:

Please indicate the primary reason(s) they are not stocked in your pharmacy.

1 Too few prescriptions presented to pharmacy

2 Inventory costs are too great

3 Lack of third-party coverage makes them unaffordable for patients

4 Time and resources involved in securing third-party payment approval (e.g., prior authorization)

5 Other [please describe]

6. Which of the following best describes your dispensing experience with Xtampza ER (oxycodone extended-release)?

Choices presented are:

- 1 Not in stock, Never dispensed
- 2 In stock, Never dispensed
- 3 Rarely (i.e., a few times a year)
- 4 Occasionally (i.e., monthly)
- 5 Frequently (i.e., daily - weekly)

If the answer to question 6 is [2-5], the respondent will go to question 7

If the answer to question 6 is [1], the respondent will be asked:

Please indicate the primary reason(s) they are not stocked in your pharmacy.

- 1 Too few prescriptions presented to pharmacy
- 2 Inventory costs are too great
- 3 Lack of third-party coverage makes them unaffordable for patients
- 4 Time/resources involved in securing third-party payment approval (e.g., prior authorization)
- 5 Other [please describe]

7. Considering your past dispensing experience, please indicate the frequency with which you have taken the following actions:

7a. Substituted a generic non-abuse-deterrent formulation opioid, when presented with a prescription for an abuse-deterrent formulation opioid.

Choices presented are:

- 1 Never
- 2 Rarely
- 3 Occasionally
- 4 Frequently

If the answer to question 7a is [1], the respondent will go to question 7b

If the answer to question 7a is [2-4], the respondent will be asked:

What circumstance(s) best describe(s) your reason(s) for substituting a generic non-abuse-deterrent formulation opioid when presented with a prescription for an abuse-deterrent formulation opioid? (select all that apply)

- 1 Patient preferred/requested non-abuse deterrent formulation
- 2 Only product stocked was non-abuse-deterrent formulation
- 3 Abuse-deterrent formulation opioid was not covered by patient insurance
- 4 Patient copay/coinsurance for the abuse-deterrent formulation was not affordable
- 5 Other

7b. Dispensed an abuse-deterrent formulation opioid when presented with a prescription written generically (e.g., dispensed Hyslingla ER for hydrocodone bitartrate, extended-release).

Choices presented are:

- 1 Never
- 2 Rarely
- 3 Occasionally

4 Frequently

If the answer to question 7b is [1], the respondent will go to question 7c

If the answer to question 7c is [2-4], the respondent will be asked:

What circumstance(s) best describe(s) your reason(s) for dispensing an abuse-deterrent formulation opioid when presented with a generically-written prescription? (select all that apply)

- 1 Patient's past medical history
- 2 General concern about potential misuse/abuse
- 3 Patient preferred / requested abuse-deterrent formulation
- 4 Only product stocked is abuse-deterrent formulation
- 5 Reimbursement for abuse-deterrent formulation is more favorable
- 6 Substitution required by state law
- 7 Other [please describe]

7c. Contacted a prescriber to recommend an abuse-deterrent formulation opioid for a patient SPECIFICALLY because of its abuse-deterrent properties

Choices presented are:

- 1 Never
- 2 Rarely
- 3 Occasionally
- 4 Frequently

Section 3. Questions about third-party payer requirements and reimbursement for abuse-deterrent formulation opioids that you have dispensed.

This question is only asked if response for questions 4, 5, or 6 = [2,3,4,5] otherwise respondent will go to question 11.

8. In general, how often do third-party payers reject the claims you submit for reimbursement?

Choices presented are:

- 1 Never
- 2 Rarely
- 3 Occasionally
- 4 Almost always
- 5 I am unsure how often claims are rejected

9. Considering your past experience, when a claim submitted for an abuse-deterrent formulation opioid was rejected, which of the following actions have you taken? (select all that apply)

Choices presented are:

- 1 Contacted the third-party payer and/or prescriber to request a prior authorization
- 2 Asked the patient to contact the third-party payer and/or prescriber to request a prior authorization
- 3 Substituted a generic non-abuse-deterrent formulation
- 4 Contacted the prescriber to request a new e-prescription for a different product
- 5 Asked the patient to contact the prescriber to get a new prescription for a different product
- 6 Allowed patient to pay cash or use copay/discount card

7 Other [please describe]

10. Considering your past experience dispensing abuse-deterrent formulation opioids, how often has high cost-sharing (i.e., copayment or coinsurance) resulted in a patient being unable or unwilling to obtain the abuse-deterrent formulation?

Choices presented are:

- 1 Never
- 2 Rarely
- 3 Occasionally
- 4 Frequently
- 5 Very frequently

11. **For FL only:** How has Florida's mandate requiring health insurance plans to provide coverage for abuse deterrent opioids affected how abuse deterrent opioid prescriptions are used compared to all opioid prescriptions?

Choices presented are:

- 1 The utilization of abuse deterrent opioid prescriptions has increased
- 2 The utilization of abuse deterrent opioid prescriptions has decreased
- 3 The utilization of abuse deterrent opioid prescriptions has not changed
- 4 Unsure
- 5 I was not aware that Florida had a mandate requiring abuse deterrent opioid coverage by health insurance companies

Alt 11 for NC only: At this time, would you support state legislation mandating third-party payer coverage of abuse deterrent opioids?

- 0 No
- 1 Yes

If Alt 11 = [0] Please elaborate as to why you would not support this legislation

If Alt 11 = [1] Please elaborate as to why you support this legislation

Section 4. Questions about your perception of opioid misuse/abuse.

12. In your professional opinion, how effective are the following strategies in mitigating the misuse/abuse of prescription opioids?

12a. Checking the prescription drug monitoring program

Choices presented are:

- 1 Not effective at all
- 2 Somewhat effective
- 3 Effective
- 4 Very effective
- 5 Unsure

12b. Pharmacist-driven pill counts

Choices presented are:

- 1 Not effective at all
- 2 Somewhat effective
- 3 Effective
- 4 Very effective

- 5 Unsure
- 12c. Abuse deterrent formulation opioids
Choices presented are:
1 Not effective at all
2 Somewhat effective
3 Effective
4 Very effective
5 Unsure
- 12d. Urine drug screening
Choices presented are:
1 Not effective at all
2 Somewhat effective
3 Effective
4 Very effective
5 Unsure
- 12e. Prescriber-driven pill counts
Choices presented are:
1 Not effective at all
2 Somewhat effective
3 Effective
4 Very effective
5 Unsure
- 12f. Payer restriction programs to a single pharmacy and/or single prescriber (e.g., lock-in program)
Choices presented are:
1 Not effective at all
2 Somewhat effective
3 Effective
4 Very effective
5 Unsure
- 12g. Prescribing (days supply) limits
Choices presented are:
1 Not effective at all
2 Somewhat effective
3 Effective
4 Very effective
5 Unsure

Section 5. Questions about you and your practice.

The following questions are asked about the characteristics of the respondents

13. What is your gender?

- Male
- Female
- Prefer not to answer
- Prefer to self-describe

14. What is your terminal degree?

- BS Pharmacy
- PharmD

15. Which of the following best characterizes your primary practice setting?

- Community pharmacy – chain/supermarket/mass merchandiser
- Community pharmacy - independent
- Health-system outpatient pharmacy
- Long-term care pharmacy
- Mail order or specialty pharmacy
- Hospital inpatient pharmacy
- Other [please describe]

16. Please indicate your total number of years in practice.

- < 5
- 5-15
- 16-25
- 26-35
- > 35

17. On average, how many total prescriptions (both controlled and non-controlled) are dispensed daily from your primary practice site?

- < 150
- 150-249
- 250-349
- 350-450
- > 450
- Unsure

Thank you for completing the survey. Your input will be valuable to us as we work to understand the utilization of abuse-deterrent formulation opioid analgesics in clinical practice.