

Request for permission for pharmaceutical industry oral testimony at Idaho Medicaid's P&T Committee meeting on 5-20-2016.

Submission # 3

As of May 5, 2016, this submission has not been accepted for oral presentation at the meeting.

Gennrich, Jane - Medicaid

From: Medical Services Mailbox <Medical_Services@pharma.com>
Sent: Tuesday, April 12, 2016 4:11 PM
To: Eide, Tamara J. - Medicaid
Subject: Information Regarding OxyContin® and Hysingla® ER
Attachments: Purdue Medical Services Response 216390.PDF; OxyContin Full Prescribing Information.pdf; Hysingla ER FPI.pdf

Dear Dr. Eide:

The following information regarding OxyContin® (oxycodone HCl) extended-release tablets and Hysingla® ER (hydrocodone bitartrate) extended-release tablets is being submitted in response to the Idaho Medicaid call for new scientific information for the upcoming Pharmacy and Therapeutics Committee meeting scheduled for May 20, 2016 that will include a review of long-acting narcotic analgesics.

If you have any questions please call us at 888-726-7535 and select option #1.

Sincerely,

Purdue Medical Services



Purdue Pharma L.P.

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Stamford, CT 06901-3431
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April 12, 2016

Tami Eide, PharmD
Idaho Medicaid
Pharmacy & Therapeutics Committee
3232 Elder Street
Boise, ID 83705

Dear Dr. Eide:

The following information regarding OxyContin® (oxycodone HCl) extended-release tablets and Hysingla® ER (hydrocodone bitartrate) extended-release tablets is being submitted in response to the Idaho Medicaid call for new scientific information for the upcoming Pharmacy and Therapeutics Committee meeting scheduled for May 20, 2016 that will include a review of long-acting narcotic analgesics.

The information beginning on the next page includes a summary of the OxyContin abuse-deterrent properties and citations to the published epidemiology studies evaluating the impact of OxyContin on abuse, misuse, and diversion of OxyContin in real-world settings. Also included is a brief summary of the Hysingla ER abuse-deterrent properties and a citation to the published intranasal clinical abuse potential study.

If we can be of further assistance, please contact Purdue Medical Services at 1-888-726-7535, prompt #1.

Sincerely,

A handwritten signature in cursive script that reads "Nancy T. Crudele".

Nancy Crudele, PharmD
Director, Medical Services

yc/YC/215737

OxyContin®

In April 2013, the FDA approved a supplemental application for reformulated OxyContin, approving changes to the product labeling that describe certain abuse-deterrent properties of OxyContin and claims in section 9.2 of the enclosed Full Prescribing Information (FPI),^{1,2} and in accordance with the FDA's 2015 Guidance on Abuse-Deterrent Opioids.³

It is important to note that not all opioid products that may have incorporated some kind of abuse-deterrent technology are recognized by the FDA.³ To date, five products have been approved with abuse-deterrent labeling claims found in Section 9.2 of their FPI, with one of the three currently available on the market being OxyContin,¹ and a second being Purdue's Hysingla® ER (hydrocodone bitartrate) extended-release tablets,⁴ as described below.

As detailed in section 9.2 of the OxyContin FPI, in vitro data demonstrate that OxyContin has physical and chemical properties that are expected to make abuse via injection difficult. The data from the clinical abuse potential study, along with support from the in vitro data, also indicate that OxyContin has physicochemical properties that are expected to reduce abuse via the intranasal route. However, abuse of OxyContin by the intravenous, intranasal, and oral routes is still possible.¹

Currently, none of the three currently available extended-release opioids with abuse-deterrent properties have labeling that includes data describing results from postmarketing epidemiology studies. At this time, OxyContin is the only product with published epidemiology studies evaluating the impact of the reformulation on abuse, misuse, and diversion of OxyContin in real-world settings. These studies are cited for your reference.⁵⁻¹¹

Hysingla® ER

Hysingla ER is formulated with abuse-deterrent properties that are recognized by the FDA with labeling claims in Section 9.2 of the enclosed Hysingla ER Full Prescribing Information (FPI).⁴

As described in section 9.2 of the Hysingla ER FPI, in vitro data demonstrate that Hysingla ER has physical and chemical properties that are expected to deter intranasal and intravenous abuse. The data from two clinical abuse potential studies (intranasal and oral), also known as "Drug Liking Studies", along with support from the in vitro data, also indicate that Hysingla ER has physicochemical properties that are expected to reduce intranasal abuse and oral abuse when chewed. However, abuse of Hysingla ER by the intravenous, intranasal, and oral routes is still possible.⁴ To date, the intranasal clinical abuse potential study has been published and is cited for your reference.¹²

OxyContin and Hysingla ER

OxyContin contains oxycodone HCl, and Hysingla ER contains hydrocodone bitartrate, both Schedule II controlled substances with a high potential for abuse. The OxyContin and Hysingla ER FPI includes a Boxed Warning describing the risks for addiction, abuse, and misuse, life-threatening respiratory depression, accidental ingestion, neonatal opioid withdrawal syndrome, and cytochrome P450 3A4 interaction.¹ Please review the enclosed OxyContin and Hysingla ER Full Prescribing Information, including Boxed Warning.

References:

1. OxyContin [Full Prescribing Information]. Stamford, CT: Purdue Pharma L.P.
2. Liscinsky M. FDA approves abuse-deterrent labeling for reformulated OxyContin [Press Release]. FDA. April 16, 2013. Web. April 2014,
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm348252.htm>
3. FDA Guidance for Industry Abuse-Deterrent Opioids- Evaluation and Labeling. US Department of Health and Human Services, Food and Drug Administration and Center for Drug Evaluation and Research. April 2015. Available at:
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidance/UCM334743.pdf> Accessed April 2016.
4. Hysingla ER [Full Prescribing Information]. Stamford, CT: Purdue Pharma L.P.
5. Sellers EM, Perrino PJ, Colucci SV, Harris SC. Attractiveness of reformulated OxyContin tablets: assessing comparative preferences and tampering potential. *J Psychopharmacol*. 2013;27(9):808-816, <http://jop.sagepub.com/content/27/9/808.long>.
6. Severtson SG, Bartelson BB, Davis JM, et al. Reduced abuse, therapeutic errors, and diversion following reformulation of extended-release oxycodone in 2010. *J Pain*. 2013; 14(10):1122-1130. <http://dx.doi.org/10.1016/j.jpain.2013.04.011>
7. Coplan PM, Kale H, Sandstrom L, Landau C, Chilcoat HW. Changes in oxycodone and heroin exposures in the National Poison Data System after introduction of extended-release oxycodone with abuse-deterrent characteristics. *Pharmacoepidemiol Drug Saf*. 2013;22(12): 1274-1282, <http://onlinelibrary.wiley.com/doi/10.1002/pds.3522/full>.
8. Butler SF, Cassidy TA, Chilcoat H, et al. Abuse rates and routes of administration of reformulated extended-release oxycodone: initial findings from a sentinel surveillance sample of individuals assessed for substance abuse treatment. *J Pain*. 2013;14(4):351-358, <http://dx.doi.org/10.1016/j.jpain.2012.08.008>.
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10. Sessler NE, Downing JM, Kale H, Chilcoat HD, Baumgartner TF, Coplan PM. Reductions in reported deaths following introduction of extended-release oxycodone (OxyContin) with an abuse-deterrent formulation. *Pharmacoepidemiol Drug Saf*. 2014;23(12):1238-1246. <http://onlinelibrary.wiley.com/doi/10.1002/pds.3658/full>
11. McNaughton EC, Coplan P, Black RA, Weber S, Chilcoat H, Butler SF. Monitoring of internet forums to evaluate reactions to the introduction of reformulated OxyContin to deter abuse. *J Med Internet Res*. 2014;16(5):e119, <http://www.jmir.org/2014/5/e119/>
12. Harris SC, Cipriano A, Colucci SV, et al. Intranasal abuse potential, pharmacokinetics, and safety of intranasally administered extended-release hydrocodone (HYD) in recreational opioid users. *Pain Med*. 2015; doi: 10.1093/pm/pnv004 [Epub ahead of print], <http://painmedicine.oxfordjournals.org/cgi/reprint/pnv004?ijkey=eZrunJIImaWz019&keytype=ref>

Enclosures:

References 1 and 4.