Abuse-Deterrent Formulations: A Private Payer View

CBI: Abuse-Deterrent Formulations Summit

March 7, 2017

Blue Cross Blue Shield Association is an association of independent Blue Cross and Blue Shield companies.
BCBSA Engages:
Public Debate on the Opioid Crisis

• White House meeting to address crisis in 2015
• PBS documentary to heighten awareness
• NGA declared opioid use one of Governors’ top five concerns in 2016
• Hosted BCBSA Congressional briefing in 2016
• Have since continued the momentum through ongoing engagements as part of BCBSA’s opioid commitment
National and State Efforts

• Supporting efforts from the White House, Congress, HHS, FDA, and CDC to combat opioid addiction and substance use disorder

• Working with the DEA, ONDCP, and NGA on developing solutions and identifying obstacles

• Aligning our work with FDA Public Health Goals for Improved Use of Prescription Opioids

• We view this as a multi-faceted problem that will take multiple solutions – no “silver bullets”
Our Strategy

PROMOTE UNDERSTANDING
Raise awareness of opioid risks and support well informed public policy through community engagements and partnerships

SUPPORT RESEARCH
Leverage resources and relationships to create a blue print for a better system of care for substance use disorder and addiction

ENSURE PATIENT-CENTERED CARE
Adhering to nationally accepted evidence-based guidelines in covering the care and treatment of individuals suffering from substance use disorder and addiction
BCBSA – Best Practices for Preventing Opioid Dependency

• Endorse CDC Guidelines for prescribing opioids for chronic pain

• Utilize pharmacy management tools to monitor and prevent over-prescribing and diversion of prescription opioids

• Adhere to nationally accepted evidence-based guidelines in covering the care and treatment of individuals diagnosed with opioid use disorder

• Engage with community partners to prevent and detect fraud and diversion of prescription opioids
Abuse-Deterrent Formulations: Our View

• We are strong supporters of maintaining access to appropriate treatment for individuals that need opioids for management of pain for acute or chronic conditions.

• Agree with FDA position that ADF technologies have not yet proven to be successful at deterring the most common form of abuse – swallowing a number of intact capsules or tablets.
  – Abuse-deterrent properties do not mean that there is no risk of abuse
  – Abuse-deterrent properties are defined as those properties shown to meaningfully deter abuse, even if they do not fully prevent abuse

• We caution that more ADFs in the marketplace are not the silver bullet to solving our national opioid epidemic.
  – For this reason, we oppose any sort of coverage mandates for ADFs.
Abuse-Deterrent Formulations: Our View

BCBSA Comments: FDA Draft Guidance on Generic ADFs

• Generic ADF products should demonstrate that they are no less abuse-deterrent than their reference listed drug with respect to all potential routes of abuse.

• Appreciate that the FDA will continue to assess the state of science and we support a continued “look-back” for both brand and generic ADFs in the market to ensure that regulations are keeping up with our collective knowledge of the issue.

• Recommend that the FDA conduct post-market surveillance of ADF products (both brand and generic) to track potential increased abuse and whether there actually is a positive impact on the opioid epidemic by having more ADF products in the community.

• The cost of ADFs also should be monitored to ensure that these drugs (both brand and generic) are not resetting the market in a way that causes untenable cost burdens on patients and payers (both public and private)
Additional Thoughts on ADFs

Does evidence exist showing ADFs decrease substance use disorder or reduce the long-term costs of substance use disorder? Are payers asking the right questions about the value of ADFs?

• ADFs may offer safety advantages over easily snorted and injected OPRs, but they do not render them less addictive. ADFs should not be considered a primary prevention strategy for opioid addiction.¹

• Opioid addiction, in both medical and nonmedical OPR users, most frequently develops through oral use.²

• Some opioid-addicted individuals may transition to intranasal or injection use, but most continue to use OPRs orally.³

• The significant cost of ADF has the potential to markedly increase costs to the health care system, given their significant expense compared to current formulations which are often generic.

Literature states that ADFs have limits in mitigating the opioid epidemic...
Literature also states that ADFs may simply shift abusers’ drug of choice...

**CORRESPONDENCE**

Effect of Abuse-Deterrent Formulation of OxyContin


_July 12, 2012_

DOI: 10.1056/NEJMc1204141

**To the Editor:**

In August 2010, an abuse-deterrent formulation of the widely abused prescription opioid OxyContin was introduced. The intent was to make OxyContin more difficult to solubilize or crush, thus discouraging abuse through injection and inhalation. We examined the effect of the abuse-deterrent formulation on the abuse of OxyContin and other opioids.

**Finding:** Our data show that an abuse-deterrent formulation successfully reduced abuse of a specific drug but also generated an unanticipated outcome: replacement of the abuse-deterrent formulation with alternative opioid medications and heroin, a drug that may pose a much greater overall risk to public health than OxyContin. Thus, abuse-deterrent formulations may not be the “magic bullets” that many hoped they would be in solving the growing problem of opioid abuse.
...and should not be considered a primary prevention strategy for opioid addiction

The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction

Andrew Kolodny,1,2,3 David T. Courtwright,4 Catherine S. Hwang,5,6 Peter Kreiner,1 John L. Eadie,1 Thomas W. Clark,1 and G. Caleb Alexander5,6,7

Some opioid manufacturers have reformulated OPRs to make them more difficult to misuse through an intranasal or injection route. These so-called abuse-deterrent formulations (ADFs) may offer safety advantages over easily snorted and injected OPRs, but they do not render them less addictive. Opioid addiction, in both medical and nonmedical OPR users, most frequently develops through oral use (85). Some opioid-addicted individuals may transition to intranasal or injection use, but most continue to use OPRs orally (47). Thus, ADFs should not be considered a primary prevention strategy for opioid addiction.
Clinicians weigh in regarding FDA generic ADF guidance

“The greater concern is whether the tamper resistance and abuse deterrence of the original formulation is sufficient. Many people abuse and misuse opioids orally, in which case tamper resistance will be essentially ineffective,” said Dr. Lewis Nelson, an emergency medicine specialist at the New York University Langone Medical Center.

“The Internet is filled with videos and blogs demonstrating ways to bypass the tamper resistant mechanisms to release drug for abuse by other routes … This effort cannot be relied upon as the major approach to reducing opioid abuse,” he said.¹

¹ https://www.statnews.com/pharmalot/2016/03/24/opioid-fda-generics-painkiller/
Speaking of blogs...

**FamilyGuy**: 04-02-2012 02:05

The little release for the new Opasna seems very similar to the ER matrix in the old Ops. I wouldn't simply crush these and expect to get much except a face full of gel. To get around the new Opasna ER use the same method as you would for Ops:

1. Crush the pills up and drip into clinic acid or something with a similar pH (you're trying to liquefy the pill of your stomach).
2. Let sit for 30 mins.
3. Drink, do not rinse/clear.

You could possibly do an A/B on these as well if you've got more time to experiment.

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**Bluitzer**: 04-05-2012 01:37

So I got the new Opasna 40's this month and at first I was fucking burned. I have been spotting Opasna for over 2 years for my back pain and I was so worried about the new ones coming out. I was worried they wouldn't work as well and after snorting for that long oral use might be deemed pointless.

Well, where there's a will there's a way. They are crush resistant, not grind proof. So I grind em up and mix in a little B12 to stop the geling... and sort of normal. Without the B12 it's like super gel... These things get up worse than ORPs... This method works amazing for OP's as well.

Anyways I got the most ridiculous nod off of em and am shocked to say I like em better... The only downside is... You gotta work for your high and grinding one on a peed or egg takes 10 minutes and will wreak havoc on your hands... I am looking into a dental tool or something of the like to make grinding easier. It only took one day to figure out grinding is stupid... Also adding Oels instead of B12 helps but as much as there is something about the consistency of B12 works really well.

So do any of you grind your new Opasna so tell us you do? I am considering a dental tool, I also heard the dog nail trimming tool. I hear it works but I am questioning the sand paper... with a tool like a drill I could do what takes 20 minutes in 30 seconds. Any ideas would be greatly appreciated. Also I hope this helped someone who has had these same issues with these pills.
The Current Environment

- Provider Education Needed
- Drug Manufacturers
- Coverage of ADFs
- Evidence of ADFs
Clinical Journal of Pain:
April 2016 - Volume 32 - Issue 4 - p 279–284
doi: 10.1097/AJP.00000000000000268
Original Articles

Primary Care Physicians’ Knowledge And Attitudes Regarding Prescription Opioid Abuse and Diversion
Hwang, Catherine S. MSPH; Turner, Lydia W. MHS; Kruszewski, Stefan P. MD; Kolodny, Andrew MD; Alexander, G. Caleb MD, MS

Abstract
Objectives: Physicians are a key stakeholder in the epidemic of prescription opioid abuse. Therefore, we assessed their knowledge of opioid abuse and diversion, as well as their support for clinical and regulatory interventions to reduce opioid-related morbidity and mortality.

Materials and Methods: We conducted a nationally representative postal mail survey of 1000 practicing internists, family physicians, and general practitioners in the United States between

Results: The adjusted response rate was 58%, and all physicians (100%) believed that prescription drug abuse was a problem in their communities. However, only two-thirds (66%) correctly reported that the most common route of abuse was swallowing pills whole, and nearly one-half (46%) erroneously reported that abuse-deterrent formulations were less addictive than their counterparts. In addition, a notable minority of physicians (25%) reported being “not at all” or “only slightly concerned” about the potential for opioid diversion from the prescription drug supply chain. Most physicians supported clinical and regulatory interventions to reduce prescription opioid abuse, including the use of patient contracts (98%), urine drug testing (90%), requiring prescribers to check a centralized database before prescribing opioids (88%), and instituting greater restrictions on the marketing and promotion of opioids (77% to 82%). Despite this, only one-third of physicians (33%) believed that interventions to reduce prescription opioid abuse had a moderate or large effect on preventing patients’ clinically appropriate access to pain treatment.

Discussion: Although physicians are unaware of some facets of prescription opioid-related morbidity, most support a variety of clinical and regulatory interventions to improve the risk-benefit balance of these therapies.
Some manufacturers eagerly pushing ADFs as the solution
That same manufacturer’s take on assigning roles and responsibilities...

<table>
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<th>Role</th>
<th>Action Steps</th>
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| Prescribers                | • Complete REMS compliance training³  
                            | • Consult section 9.2 to determine abuse-deterrence status of an opioid      |
|                            |     product²  
                            | • Prescribe opioids appropriately¹                                           |
| Pharmacists                | • Increase awareness of prescription drug abuse and misuse and the availability |
|                            |     and benefits of opioids with abuse-deterrent properties¹  
                            | • Consult section 9.2 to determine abuse-deterrence status of an opioid      |
|                            |     product²                                           |
| Payers                     | Form partnerships with stakeholder agencies to develop reimbursement         |
|                            |     strategies that ensure patients in pain receive opioids with abuse-      |
|                            |     deterrent properties when appropriate²                        |
| Policymakers               | Provide guidance to the pharmaceutical industry on the development of       |
|                            |     abuse-deterrent drug formulations and on postmarket assessment of their  |
|                            |     performance³                                                      |
| Pharmaceutical Manufacturers| Develop abuse-deterrent opioid formulations⁴                          |
| Patients                   | Take appropriate action to safeguard prescription opioids from abuse, misuse,|
|                            |     and diversion and ensure their proper disposal¹                  |
| Parents and Community      | Educate children about the risks associated with prescription opioids¹     |
| Leaders                    |                                                                           |
2016 State Activity on ADFs

2016 Legislative Landscape:
Abuse-Deterrent-Formulation (ADF) Drugs

ADF Legislation Introduced But Did Not Pass (Or Has Not Progressed Yet)

ADF Study Bill Passed
- 2014 ADF Legislation Passed
- 2015 ADF Legislation Passed
- 2016 ADF Legislation Passed

No ADF Legislation Introduced

Note: Map is as of May 11, 2016.
Some states are taking a cautious approach

While the intent of this bill is laudable, research on the impacts of utilizing abuse-deterrent drugs is in its infancy. The effectiveness of such drugs is currently under review, and it is simply too early to tell whether it would achieve its intended effects...abuse-deterrent opioid drugs are approximately two to three times more expensive on a daily basis than opioid drugs that lack abuse-deterrent properties, thus resulting in increased, and unplanned, costs to the State and consumers.

**GOVERNOR ANDREW CUOMO (D-NY)**
Veto message for AB 7427-A (no. 284), December 11, 2015

In addition to the lack of clarity regarding the efficacy of these drugs, abuse-deterrent opioids cost approximately three times more than opioids without these formulations. By all accounts, this bill will cost the State over $11 million each year, the benefits of which, as noted, are still uncertain.

**GOVERNOR CHRIS CHRISTIE (R-NJ)**
Veto message for AB 4271, January 19, 2016
Evidence-Based Solutions to the Opioid Crisis

• BCBSA: What’s Next?
• Example 1: Review coverage and utilization management tools, re: medication-assisted (MAT) drugs (e.g., buprenorphine)
• Example 2: Review evidence for nonpharmacological treatment for pain
• What is the value proposition for ADFs?
  – reduction in substance use disorder (Category 4 products)
  – reduction in diversion
• Are payers asking the right questions about the value of ADFs?
Closing Thoughts

• A multi-faceted approach will be necessary to even begin to tackle this epidemic – no single solution is going to be the answer

• Collectively we need to consider how to prevent addiction while also building support for those who need treatment

• ADFs are still unproven, and while they may benefit some individuals the fact remains that they can still be abused
  – Evidence needs to catch up with the marketing of ADFs

• Incentives should be in place to encourage the development of innovative, effective, abuse-deterrent products but more proof is needed before any widespread coverage will be embraced

• Education on ADFs is essential
Contact Information

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