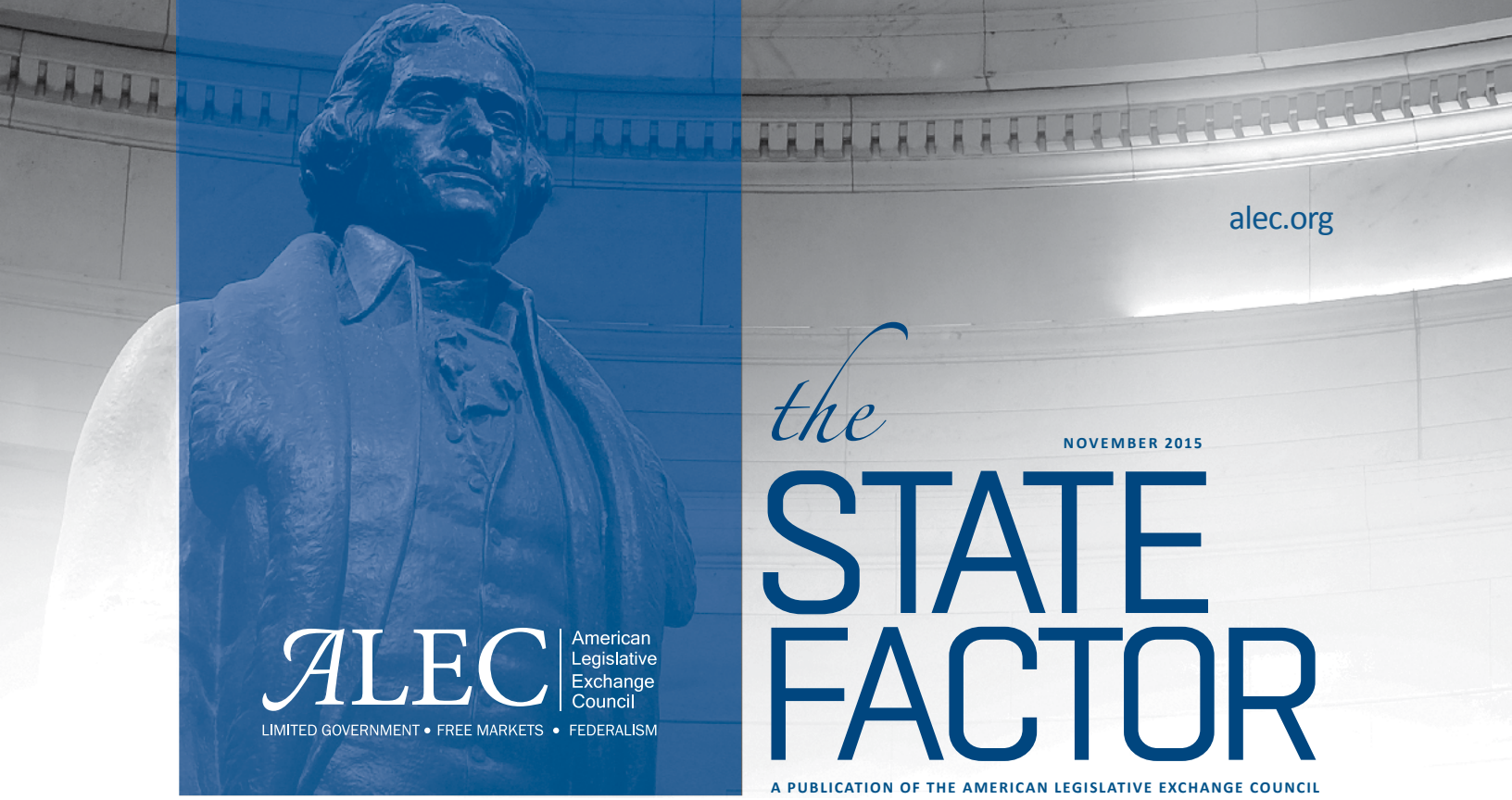

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Optimizing the Abuse-deterrent Opioids Market

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Introduction

The U.S. health care system is rife with problems that have been mounting for years. Costs are unaffordable. Quality is diminishing. And regulatory costs are over-burdening too many health care providers. Sustainably fixing the U.S. health care system requires fundamental reforms that address the inefficiencies and adverse incentives that plague the current system. Unfortunately, it is unlikely that fundamental health care reform will be implemented anytime soon.

Lack of progress on fundamental health care reform does not mean targeted reforms within our current system should not be pursued. Targeted reforms can address specific issues that are driving health care costs higher and reducing the quality of care for patients. Legislation that removes the current systemic biases against abuse-deterrent opioid usage (also referred to as abuse-deterrent formulations or ADFs) exemplifies the benefits that can be gained through effective targeted reforms.

Prescription opioids are an important therapy that help patients manage their pain more effectively–whether that pain is chronic or short-term (e.g. post-injury or post-surgery). Studies illustrate that prescription opioids can effectively manage short-term pain conditions, lower health care expenses related to long-term chronic pain, and reduce workplace costs associated with employees who suffer from long-term chronic pain.

There is a downside to opioids, however. While an important treatment option for pain patients, prescription opioid abuse (e.g. the use of opioid medication for non-medical reasons) and opioid diversion (e.g. when pain medications legally prescribed

are illicitly transferred to someone other than the patient) have become chronic problems in the United States. The prescription opioid abuse and diversion problem adds significant costs to public and private payers, employers, and is an increasing burden on our criminal justice system.

Abuse-deterrent opioids are a new medicine designed to help address this problem. Initial studies are finding that abuse-deterrent opioids, particularly when used in coordination with other tools, help lower the problem of prescription opioid abuse and diversion. With less prescription opioid abuse, the overall healthcare, workplace, and criminal justice costs associated with this growing societal problem are lessened.

Whether a patient should be prescribed an abuse-deterrent opioid instead of a non-deterrent opioid formulation is a medical decision that should be made between doctors and patients. However, some states have regulatory and legislative barriers in place that make it more difficult for patients to avail themselves of the new abuse-deterrent opioid formulations.

The availability of ADFs are currently limited and therefore cost more than non-abuse-deterrent opioid formulations, which may sometimes discourage the use of ADFs in cases when these medicines would be valuable. However, healthcare expenditures, just like patients' treatment plans, should be viewed systemically. Spending more money on a treatment that lowers overall health care expenditures, and/or improves overall health outcomes, is a benefit that should be encouraged. Therefore, policies that allow for more open rules in prescribing abuse-deterrent opioids are important reforms that should be considered.

More importantly, by reducing other health care costs, pharmaceuticals often lead to a net reduction in health care expenditures. Policies that discourage pharmaceutical use, as is the case with ADFs, can ultimately lead to reduced patient benefit and increased health care expenditures.

Based on the below studies, legislation and regulations that empower doctors to prescribe this new medicine, if they deem it appropriate, would help reduce the unnecessary health care, workplace and criminal justice costs created by prescription opioid abuse while ensuring that pain patients can still receive medically necessary therapies.

Before these issues are addressed, however, this paper reviews the costs of pain. Understanding the large costs created by pain provides context regarding why prescription opioids are valuable medications for patients. The value from abuse-deterrent opioids, consequently, is derived from their ability to ensure pain patients receive their medications while reducing the unintended costs created by opioid abuse.

Prescription Opioids and Pain Management

Chronic pain is a widespread problem. Approximately 100 million Americans suffer from some level of chronic pain, more than the number of Americans suffering from diabetes (25.8 million, including diagnosed patients and estimated undiagnosed patients), heart disease (16.3 million) cancer (11.9 million), and stroke (7.0 million) combined.[1]

Pain disorders include headache, lower back pain, arthritis and other joint pain.[2] Chronic pain can also be due to past injuries, or specific conditions such as inflammatory disorders like rheumatoid arthritis, fibromyalgia or neuropathy (nerve damage). Cancer patients and cancer survivors (such as breast cancer, prostate cancer, and lung cancer) will also often experience chronic pain, which can be caused by the cancer treatment or the disease itself. [3]

People suffering from untreated chronic pain use the health care system more than people who are not suffering from chronic pain. People suffering from chronic pain typically require more emergency room visits, higher amounts of other hospital expenditures that sometimes include surgeries (that may not, in some cases, even be necessary), higher medica-

tion costs, and higher psychological costs such as the treatment of depression that often results from the inability to properly manage pain.

The additional healthcare costs associated with chronic pain are estimated to be between $261 billion and $300 billion annually.[4] These health care costs are borne by payers–both private insurance companies and government health programs (e.g. Medicare and Medicaid)–as well as by providers, hospitals, and the patients themselves.

People suffering from chronic pain are also less productive at work. Brownlee et al. (1997) reported that "pain results in one quarter of all sick days taken, or 50 million in lost workdays a year."[5] Rasor and Harris estimated that chronic pain is the second-leading cause of absenteeism from work, following the common cold.[6]

Stewart and Ricci (2003) estimated the costs of chronic pain on productivity due to employee absenteeism and the reduced productivity of employees who reported to work but were in pain.[7] The majority (76.6 percent) of the measured productivity losses were due to reduced performance while at work.

All of this lost productivity, and the workplace costs from pain, account for $299 billion to $335 billion. Aggregating these costs, chronic pain imposes between $560 billion and $635 billion[8] in total costs on the U.S. economy each year–about 47 percent of these costs directly borne by the health care system, see Figure 1.

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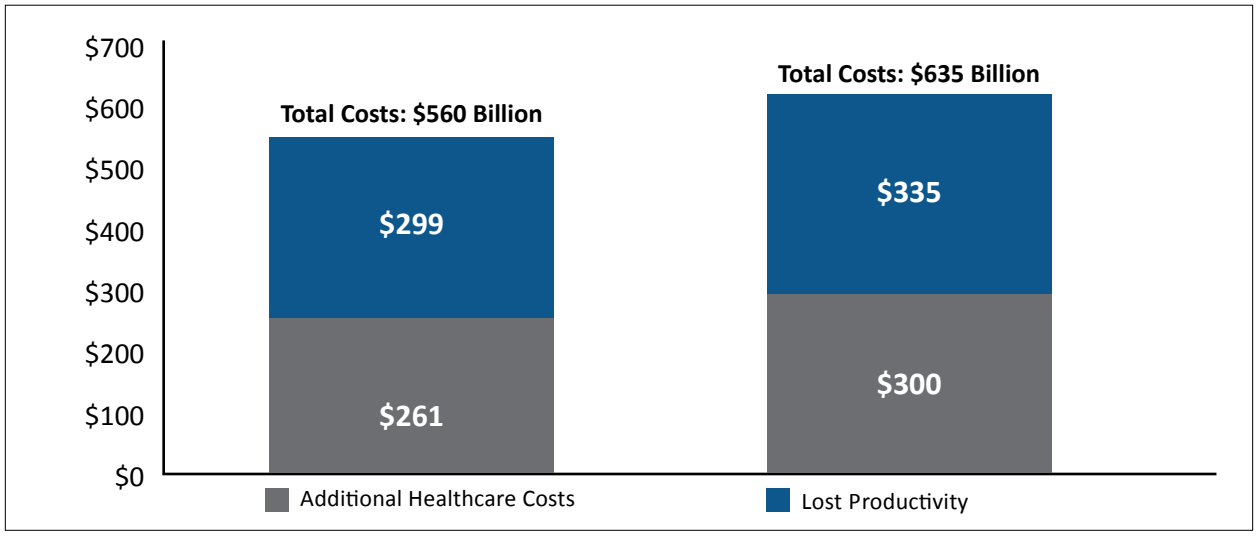
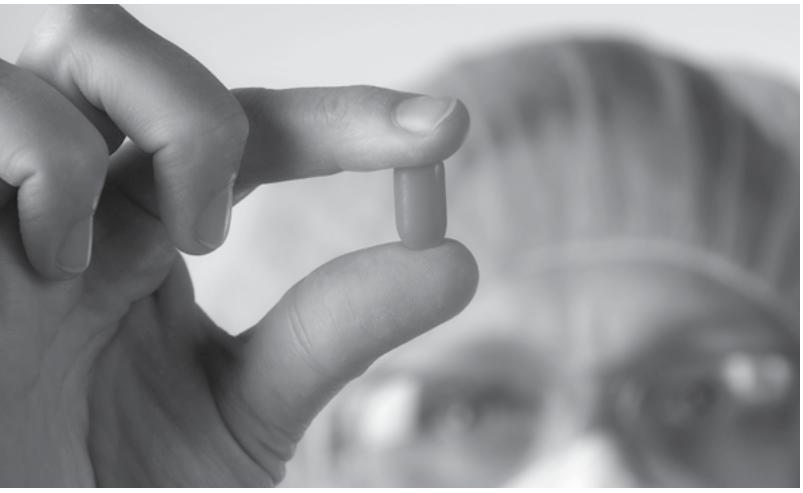
Figure 1 Estimated Aggregate Cost of Chronic Pain as of 2009 (in 2010 Dollars)





There are also indirect costs from pain, including mild chronic pain that patients suffer, that, while significant, are not included in these estimates. Studies have attempted to ascertain pain patients' *subjective* assessment of the value from pain relief (referred to as "willingness to pay" studies) showing that patients highly value effective therapies due to the significant improvement in their quality of life. As an example of these results, Chuck et al. (2009) found that chronic pain patients would be willing to pay $1,428 *per month* (i.e. $17,136 per year) to completely minimize pain-related morbidity, and that the patients were primarily concerned with reduction in the intensity of the pain (versus regaining functionality).[9]

In 2012, the pain management drugs and devices market was $35.4 billion, and is expected to grow 3.2 percent a year reaching $41.5 billion in 2017.[10] Additionally, a 2007 survey by the National Center for Health Statistics found that Americans spent $34 billion on complementary and alternative medicines (such as chiropractors and acupuncture) in a single year–nine of the top 20 conditions contained in the survey involved chronic pain.[11]

Pain is not only a chronic problem, however. Patients will often experience severe, but temporary, pain post-surgery or following a traumatic injury. While the cost estimates above focus on the costs imposed from chronic pain, there is also a need to manage pain for patients suffering on a temporary, or short-term, basis as well.

Studies indicate that prescription opioids are an effective treatment option that is appropriate for some patients suffering with pain that helps them manage their pain affliction. For instance, according to Brownlee et al. (1997)

> *…morphine, methadone, and codeine [opioids] are routinely given to patients in acute, temporary pain--after a car wreck or major surgery, for example. They can blunt even the most savage pain in 90 to 95 percent of terminal cancer patients, according to a decade of work by pain specialists Drs. Kathleen Foley and Russell Portenoy of Memorial Sloan-Kettering Cancer Research Center.*[12]

A panel of pain experts convened by the *Mayday Fund* similarly found that doctors treating patients need access to a wide variety of treatment options, including opioids, in order to effectively help pain patients:

> *Individuals with chronic pain often need a combination of multiple daily medications, and sometimes opioids (strong pain medications), psychological, behavioral and social interventions, rehabilitation therapy, and complementary treatments. Because of the level of pain, some patients should also be offered more interventions, such as injection therapies, nerve blocks, or trials of implanted therapies.*[13]

In another study, Rasor (2007) noted that when patients are suffering from pain, "adequate treatment is necessary to allow patients to have a meaningful and productive life. Prescription opioid use for pain management allows successful restoration of this ability."[14]

Prescription opioids are also associated with reductions in the excessive health care costs associated with chronic pain. According to an Institute of Medicine study:

> *Pain prevention…offers the prospect of substantial savings in U.S. health care costs. The analysis conducted for this study found that on average, a person with moderate pain generates health care expenditures $4,516 higher than those for a person without pain. A person with severe pain generates health expenditures $3,210 higher than those for a person with moderate pain. The precise reasons for these large cost differences are unclear; to the extent that they reflect differential utilization of health services due to pain, however, the potential cost savings if pain were prevented or treated more effectively are enormous.*[15]

But, there are also risks and potential side effects from prescription opioids. Rasor (2007) also notes,

> *They [opioids] are powerful analgesics that can produce life-threatening toxicities; therefore, both physician and patient should carefully evaluate the risk-to-benefit profile of opioids.*[16]

Managing these risks, require, in part, a comprehensive treatment plan which should include:

- *selection and use of the appropriate opioid,*
- *involvement of other healthcare providers, as warranted,*
- *osteopathic manipulative treatment (OMT), as appropriate, and*
- *patient education.*

The addictive properties of prescription opioids also require physicians and patients suffering with pain to manage the risks of addiction as well. As Express Scripts noted, prescription opioids "…are most effective in providing relief to patients suffering from severe pain; however, their extremely addictive properties pose a serious risk to patients, and make them prone to misuse and abuse."[17] It is the problem of opioid abuse and misuse that the abuse-deterrent formulations have been designed to address. And, as outlined in the next section, these costs have become very large.[18]

Prescription Opioid Abuse and Misuse: an Unintended Consequence of Opioid Therapies

Although prescription opioids can create great value for patients in managing their pain, prescription opioid abuse has become the largest drug abuse problem in the country. According to the Department of Health and Human Services (HHS):

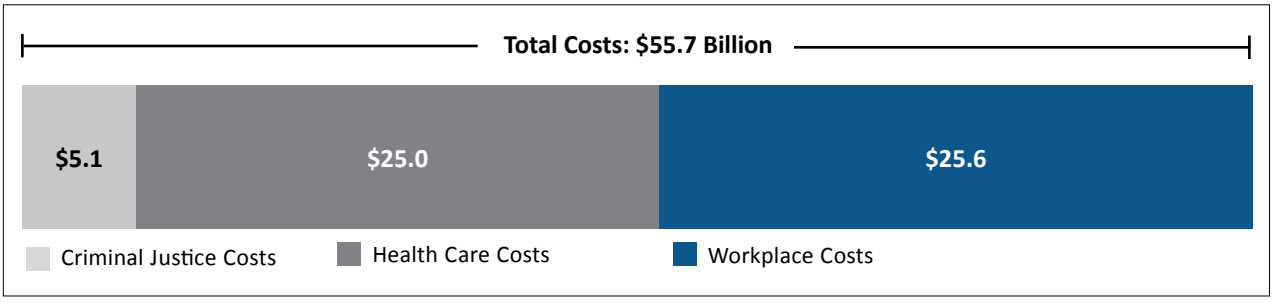
> *[Prescription] Opioids, alone or in combination with other drugs or alcohol, were involved in 30 percent of drug overdose deaths where a drug was specified in 1999, compared to nearly 60 percent in 2010. In 2010 alone, opioid analgesics were involved in 16,651 deaths–far exceeding deaths from any other drug or drug class, licit or illicit.*

Confirming these results, Moorman-Li et al. (2012) found that the problem of prescription opioid abuse is growing, stating that "abuse rates having quadrupled in the decade from 1990 to 2000.[19] According to the Substance Abuse and Mental Health Services Administration, approximately 15.7 million people aged 12 or older have used prescription drugs non-medically in the past year.[20]

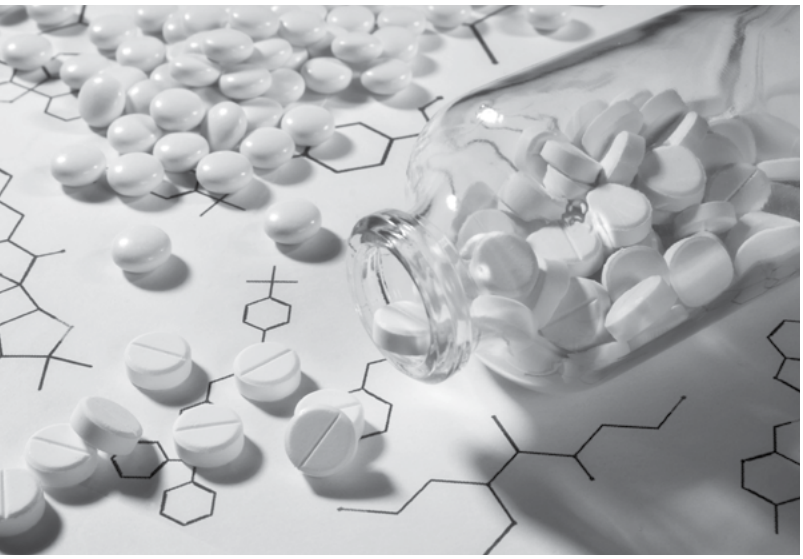
Individuals who abuse pain medication incur higher healthcare costs compared to individuals who do not abuse pain medication. According to a study by White et al. (2005), the "mean annual direct health care costs for opioid abusers were more than eight times higher than for non-abusers ($15,884 versus $1,830, respectively…)".[21] It is not just higher healthcare costs, however. Individuals who abuse pain medication are also less productive at work, creating workplace costs.

The combination of higher costs caused by individuals abusing pain medication, coupled with the large number of individuals abusing these medicines, has led to a large aggregate cost from opioid abuse. Birnbaum et al. (2011) estimate that "total US societal costs of prescription opioid abuse were estimated at $55.7 billion in 2007 (the estimates are reported in 2009 dollars), see Figure 2. Workplace costs accounted for $25.6 billion (46 percent), health care costs accounted for $25.0 billion (45 percent), and criminal justice costs accounted for $5.1 billion (9 percent)."[22]

Figure 2 Estimated Aggregate Cost of Abuse of Opioid Medications as of 2008 (in 2009 Dollars)



The Birnbaum et al. findings are typical according to a comprehensive review of the literature performed by Strassels (2009). Strassels (2009) examined 41 papers that assessed the economics and epidemiology of prescription opioid abuse or misuse in the United States. According to Strassels, the literature finds that, "the costs associated with opioid abuse and misuse are large and represent a significant societal burden. While efforts to decrease the epidemiologic and economic burden of opioid misuse and abuse are important, pain is commonly poorly managed in the United States. Thus, it is important to ensure that efforts to reduce opioid abuse and misuse do not adversely affect appropriate access to these drugs for pain management."



Addressing Prescription Opioid Abuse While Still Ensuring Access to Necessary Therapies

The health challenge is to balance the legitimate need for opioid medications for pain patients while minimizing problems created by prescription opioid abuse. Successfully balancing these issues require a combination of tools to minimize prescription opioid abuse and diversion, some which include:

- Education efforts of patients by physicians that should also include physician-patient contracts;
- Prescription monitoring programs;
- Serially numbering prescriptions;
- Photo ID requirements for patients when picking up their medicines from the pharmacy;
- Urine drug toxicology screening;
- Clinical questionnaires and screening tools to identify individuals at risk for misusing or abusing opioid analgesics;
- Enhanced efforts to monitor controlled substances from manufacturer to pharmacy to reduce theft during the distribution process; and,
- Safe disposal provisions for unused opioids.[26]

Research is also showing that abuse-deterrent formulations bring significant value in enhancing the efficacy of the current methods (listed above) for minimizing the problem of opioid abuse and diversion. For instance, in discussing this balancing act, the *Tufts Health Care Institute Program on Opioid Risk Management* noted that, "unrelieved pain and prescription opioid abuse are inextricably interconnected public health problems. The development of abuse-deterrent formulations (ADFs) of prescription opioids is among the most important balanced risk management approaches to improving access to pain relieving treatment, while decreasing opioid abuse."[27]

Abuse-deterrent opioids are a relatively new and dynamic approach for managing the opioid abuse problem. Three new abuse-deterrent drugs have been approved recently and several new technologies and medicines (both branded and generic) are currently under development. Hahn (2011) explains that abuse-deterrent opioids work in one of three general approaches:

- *The "fortress approach," in which the formulation maintains its extended-release characteristics despite attempts to crush or dissolve it*
- *The "neutralizing approach," in which the formulation is relatively easy to alter, but tampering with the formulation results in the release of a neutralizing antagonist*
- *The "aversive approach," in which the opioid is formulated with an aversive agent that results in un-pleasant side effects when a large quantity of the opioid is ingested.*[28]

Most abuse-deterrent opioids have been recently approved, and therefore the impact from abuse-deterrent opioids on reducing opioid abuse and diversion is a new research field. However, as should be expected with new innovative technologies, studies of the effectiveness of abuse-deterrent opioids are starting to be published. These studies are illustrating

that abuse-deterrent opioids are associated with reductions in abuse and misuse, and that abuse-deterrent opioids are having a positive benefit with respect to the costs of the opioid abuse problem.

Larochelle (2015) examined the effect from two changes in the prescription opioid market–the introduction of an abuse-deterrent opioid (abuse-deterrent extended-release oxycodone hydrochloride) and withdrawal from the market of propoxyphene–on total opioid dispensing and total opioid abuse.[29] With respect to opioid abuse, the authors found that two years following the market change, estimated opioid overdose rates decreased 20 percent.

Rossiter et al. (2014) estimated how the introduction of an extended-release (ER) version of oxycodone HCI with abuse-deterrent technology changed medical costs.[30] The authors found that "the introduction of reformulated ER oxycodone was associated with relative reductions in rates of diagnosed opioid abuse of 22.7 percent and 18.0 percent among commercially-insured and Medicaid patients, respectively."[31]

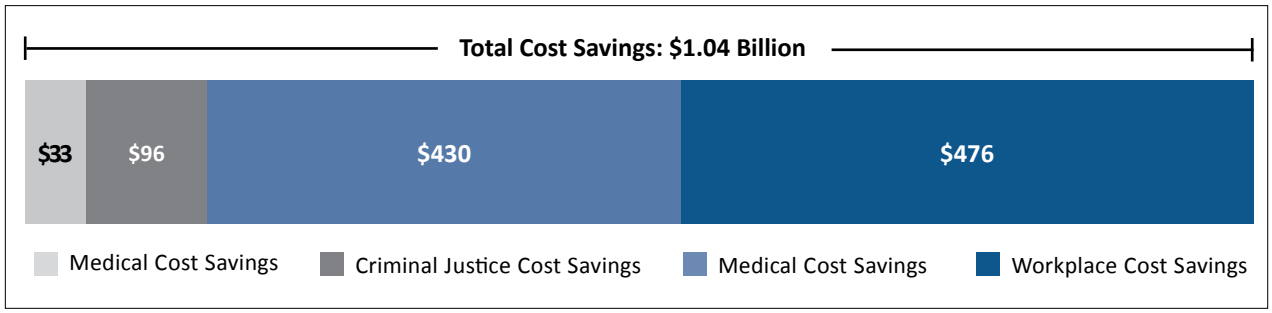
Rossiter et al. (2014) also found that the excess annual per-patient medical costs associated with diagnosed opioid abuse were $9,456 for commercially-insured patients and $11,501 for Medicaid-insured patients.[32] The authors found that "overall, reformulated ER oxycodone was associated with annual medical cost savings of $430 million in the US."[33]

Kirson et al. (2014) further notes "medical cost savings reported in Rossiter et al. are an underestimate of the full societal economic benefits of reformulated ER oxycodone, as prescription opioid abuse is also associated with higher rates of medical resource utilization and costs among caregivers and substantial workplace and criminal justice costs."[34]

These studies are illustrating that abuse-deterrent opioids are associated with reductions in abuse and misuse, and that abuse-deterrent opioids are having a positive benefit with respect to the costs of the opioid abuse problem.

Kirson et al. (2014) label these as indirect cost savings. In total, they estimate that abuse-deterrent opioids could reduce indirect costs by $605 million, for a total cost reduction from reformulated ER oxycodone (including medical costs) of $1.04 billion, see Figure 3.[35]

Figure 3 Estimated Aggregate Cost Reduction Due to Reformulated ER Oxycodone (ADF)



The estimated $1.04 billion in reduced medical and indirect costs associated with the abuse of opioid medications shows the significant benefits abuse-deterrent opioids can create. These results indicate that abuse-deterrent formulations have great potential in addressing the problem of opioid abuse while still ensuring pain patients can receive the medicines they require–particularly when used in combination of other tools that help doctors appropriately prescribe and monitor their pain patients.

While the evidence to date has shown that abuse-deterrent formulations are a valuable medical option, currently, that value comes with a cost. Abuse-deterrent formulations are patented products while many non-deterrent formulations are available in generic versions as well as patented versions. These higher costs are temporary, however.

Eventually, more generic versions of abuse-deterrent formulations will enter the market, driving down the average price paid for abuse-deterrent opioids. Additionally, ADFs make it more difficult to abuse prescription opioids. While not fool-proof, the greater difficulty in abusing prescription opioids should help reduce the number of opioids that are obtained with the sole purpose of being abused. Both of these effects will help lower the total health care expenditures on prescription opioids over time.

Due to the current dominance of patented products in the abuse-deterrent market, prices for abuse-deterrent formulations will tend to be higher. As a consequence, growing market share for ADFs will likely increase overall healthcare expenditures for opioids on a prescription-to-prescription basis in the near-term.

The combination of the inefficiencies of our health care system combined with the higher price for abuse-deterrent opioids creates disincentives that can thwart the benefits that abuse-deterrent opioids can offer.

Current Inefficiencies That Should Be Addressed

Doctors should be empowered to prescribe abuse-deterrent opioids when these medicines are appropriate. There are many tools to help doctors determine when an abuse-deterrent opioid is appropriate for a patient, and when a non-abuse-deterrent opioid is appropriate for a patient.

A clinical questionnaire is an excellent example. Doctors use clinical questionnaires to identify risk factors for potential opioid abuse. If a clinical questionnaire reveals that a patient has a specified at-risk profile for opioid abuse, such as a parent living with an at-risk teenager, then a doctor may determine that an abuse-deterrent opioid prescription, rather than a prescription for non-deterrent formulation, is appropriate. In such circumstances, the doctor should be empowered to prescribe an ADF, and that decision should be respected by the payers.

Unfortunately, actions that interfere in this doctor-patient relationship and discourage the use of ADF medicines due to their higher average prescription price is an issue that needs to be addressed in most states. These practices include third party payers or pharmacists substituting a generic non-abuse-deterrent formulation for a patient without receiving written permission from the prescribing health care provider. They also include requiring pre-authorization requirements that are excessive relative to other opioid medications.

Similarly, a patient will often be required to use a non-abuse-deterrent opioid first, and then, only if this approach fails, can he or she be prescribed an abuse-deterrent opioid. Such requirements should not be applicable in the case of abuse-deterrent opioids. Failure for a non-abuse deterrent opioid is not due to the medicine failing to control the patient's pain–medical inefficacy is the typical justification for these requirements. Instead, failure occurs because either the patient, or someone who has been able to obtain the patient's medicine, has abused the medication.

Correcting the dis-incentives that discourage appropriate use of abuse-deterrent opioids is a reform opportunity that addresses an important health need, reduces overall health care expenditures, lowers criminal justice costs, and beneficially impacts overall workplace productivity. Effective and targeted legislation can address these dis-incentives, allowing the abuse-deterrent opioids to compete in the medical marketplace based on their medical efficacy.

Effective Legislative Reforms

Health care reform should empower doctors and patients to make the medical decisions that are appropriate for each individual patient. Targeted reforms that correct the disincentives to prescribe ADFs, by ensuring parity between how abuse-deterrent opioids are treated and how other pharmaceutical products are treated, are consistent with this goal. Specifically, states should implement targeted legislative reforms that:

- Require written permission from a health care provider before a prescription for an abuse-deterrent formulation can be switched into a non-abuse-deterrent formulation; and,
- Prohibit patients from being required to use a non-abuse-deterrent prescription before an abuse-deterrent formulation can be prescribed.

Beyond legislation that ensures parity for ADFs in the marketplace, elected and agency officials should also consider including ADFs on formularies and preferred drug lists for state paid health insurance programs, including Medicaid. As documented above, abuse-deterrent opioids have the potential to create significant health care savings, as well as reductions in criminal justice costs. Currently, the excessive health and criminal costs are burdening state budgets. By including abuse-deterrent opioids on the state formularies, states can ensure pain patients who are on state-paid health insurance programs have access to their necessary medicines while reducing the incidence of prescription opioid abuse, and, consequently, reducing overall health care and criminal justice costs–a win-win-win solution.

Elected and agency officials should also consider implementing advanced analytics in their prescription drug monitoring programs that would benefit ADFs as well as prescription drugs more broadly. Currently, there is a prescription drug monitoring program in 49 states (Missouri stands alone as the only state in the union to not have any kind of prescription drug monitoring program).

Most state prescription drug monitoring databases simply collect prescription data; the states do not proactively analyze the data to find inappropriate or suspicious behaviors. Adopting advanced analytics–such as anomaly detection, predictive modeling, and social network analysis–empowers health professionals to confidentially evaluate millions of prescription records, almost instantaneously, and pinpoint highly suspicious behaviors while allowing the vast majority of compliant physicians to treat patients as they deem medically appropriate.

Due to the novelty of ADFs, however, some states might prefer an intermediate step. In such cases, elected officials should pass legislation that asks the insurance commissioner (or appropriate research organization) to study the health and economic efficacy of abuse-deterrent opioids.

It is important for elected officials to neither encourage nor discourage the use of ADFs. For instance, there are some proposals that would mandate doctors only prescribe abuse-deterrent formulations. Excessive mandates and a lack of empowerment between doctors and patients are part of the U.S. health care system's problems. Just as doctors should have the ability to prescribe abuse-deterrent opioid formulations if they believe these medicines best serve their patient's interests, they should also have the ability to prescribe non-abuse-deterrent formulations if they believe these medicines best serve their patient's interests.

The goal of ADF legislation should be to enable the abuse-deterrent market and reduce barriers that interfere with the medication decisions that are made between doctors and patients. Effective ADF legislation should not create new barriers.

Concluding Thoughts

Pain is a large medical problem in the U.S. The total health care and economic costs from chronic pain are estimated to be as high as $635 billion a year. Prescription opioids provide relief for people suffering from chronic pain, and also help people suffering from short-term pain conditions–such as pain following traumatic injuries or post-surgery.

However, abuse of prescription opioids has also become a large societal problem. Opioids are now the most oft-abused drugs in the country responsible for more than 16,000 deaths a year and $55.7 billion in health care, workplace, and criminal justice costs a year. Consequently, the health care community requires new tools to ensure that pain patients can still have access to their medicines while helping to reduce the incidence of prescription opioid abuse.

Abuse-deterrent opioids have illustrated great value in meeting these goals. While still novel, the initial studies are showing that abuse-deterrent opioids have a meaningful impact in reducing the incidence of opioid abuse.

State elected and agency officials can play an important role in supporting this technology. Barriers, such as requirements that pain patients must first use non-abuse-deterrent opioids before they can be prescribed an abuse-deterrent opioid, are limiting the number of patients who are benefiting from ADFs. Therefore, elected and agency officials should support policies that eliminate these barriers and empower doctors and patients to choose abuse-deterrent opioids when they believe it would be most beneficial.

[End Notes]

1. "AAPM Facts and Figures on Pain" the American Academy of Pain Medication; http://www.painmed.org/patientcenter/facts_on_pain.aspx#incidence. Accessed September 9, 2015. Data is cited to: Institute of Medicine Report from the Committee on Advancing Pain Research, Care, and Education: Relieving Pain in America, A Blueprint for Transforming Prevention, Care, Education and Research. The National Academies Press, 2011; http://books.nap.edu/openbook.php?record_id=13172&page=1; American Diabetes Association. http://www.diabetes.org/diabetes-basics/diabetes-statistics/; Heart Disease and Stroke Statistics—2011 Update: A Report From the American Heart Association. Circulation 2011, 123:e18-e209, page 20; http://circ.ahajournals.org/content/123/4/e18.full.pdf; American Cancer Society, Prevalence of Cancer: http://www.cancer.org/docroot/CRI/content/CRI_2_6x_Cancer_Prevalence_How_Many_People_Have_Cancer.asp.
2. Rasor, Joseph and Gerald Harris (2007) "Using Opioids for Patients With Moderate to Severe Pain." J Am Osteopath Assoc. 2007; 107(suppl 5):ES4-ES10; (2009).
3. http://www.livestrong.org/we-can-help/finishing-treatment/chronic-pain/.
4. Gaskin, Darrell J. and Richard, Patrick (2012) "The Economic Costs of Pain in the United States" Journal of Pain Vol. 13 No. 8 August; http://www.ncbi.nlm.nih.gov/pubmed/22607834.
5. Brownlee, Shannon, Joannie M. Schrof, Beth Brophy, and Mary Brophy Marcus (1997) "The Quality of Mercy: Effective pain treatments already exist. Why aren't doctors using them?" U.S. News and World Report, 3/17, p. 54-57, 60, 62, 65, 67, www.doctordeluca.com/Library/Pain/QualityOfMercy97.htm.

   See also, "A Call to Revolutionize Chronic Pain Care in America: An Opportunity in Health Care Reform." Mayday Fund November 4, http://www.maydaypainreport.org/.
6. Rasor, Joseph and Gerald Harris (2007) "Using Opioids for Patients With Moderate to Severe Pain." J Am Osteopath Assoc. 2007; 107(suppl 5):ES4-ES10; (2009).

   See also, Stewart, Walter F., Ricci, Judith A., Chee E, Morganstein D, Lipton R. (2003) "Lost productive time and cost due to common pain conditions in the US workforce" JAMA 2003; 290(18): 2443-2454; http://www.ncbi.nlm.nih.gov/pubmed/14612481.
7. Stewart, Walter F., Ricci, Judith A., Chee E, Morganstein D, Lipton R. (2003) "Lost productive time and cost due to common pain conditions in the US workforce" JAMA 2003; 290(18): 2443-2454; http://www.ncbi.nlm.nih.gov/pubmed/14612481.
8. Gaskin, Darrell J. and Richard, Patrick (2012) "The Economic Costs of Pain in the United States" Journal of Pain Vol. 13 No. 8 August; http://www.ncbi.nlm.nih.gov/pubmed/22607834.
9. Chuck, Anderson, WiktorAdamowicz, Philip Jacobs, ArtoOhinmaa, Bruce Dick, and SaifudinRashiq. 2009. "The Willingness to Pay for Reducing Pain and Pain-Related Disability." Value in Health, Vol. 12, Issue 4, pp. 498-506, June.
10. (2013) "The Global Market for Pain Management Drugs and Devices" bcc Research, January; http://www.bccresearch.com/market-research/healthcare/pain-management-drugs-devices-hlc026d.html.
11. Boyles, Salynn (2009) "Americans Spend $34 Billion on Alternative Medicine." WebMD; http://www.medscape.com/viewarticle/706996.
12. Brownlee, Shannon, Joannie M. Schrof, Beth Brophy, and Mary Brophy Marcus (1997) "The Quality of Mercy: Effective pain treatments already exist. Why aren't doctors using them?" U.S. News and World Report, 3/17, p. 54-57, 60, 62, 65, 67, www.doctordeluca.com/Library/Pain/QualityOfMercy97.htm.
13. (2009) "A Call to Revolutionize Chronic Pain Care in America: An Opportunity in Health Care Reform" The Mayday Fund, November 4; Amended March 4, 2010.
14. Rasor, Joseph and Gerald Harris (2007) "Using Opioids for Patients With Moderate to Severe Pain." J Am Osteopath Assoc. 2007; 107(suppl 5):ES4-ES10; (2009).
15. (2011) Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. Washington (DC): National Academies Press (US); http://www.ncbi.nlm.nih.gov/books/NBK92516/.
16. Rasor, Joseph and Gerald Harris (2007) "Using Opioids for Patients With Moderate to Severe Pain." J Am Osteopath Assoc. 2007; 107(suppl 5):ES4-ES10; (2009).
17. (2014) "A Nation in Pain: Focusing on U.S. Opioid Trends for Treatment of Short-term and Longer-term Pain" Express Scripts, December.

18. Behavioral Health Coordinating Committee Prescription Drug Abuse Subcommittee "Addressing Prescription Drug Abuse in the United States Current Activities and Future Opportunities" U.S. Department of Health and Human Services.

19. Moorman-Li, Robin, Carol A. Motycka, Lisa D. Inge, Jocelyn Myrand Congdon, Susan Hobson, and Brian Pokropski, (2012)" A Review of Abuse-Deterrent Opioids For Chronic Nonmalignant Pain" P&T July Vol. 37 No. 7. To substantiate the claim the authors cited: National Institute on Drug Abuse (NIDA) (2005) "NIDA Community Drug Alert Bulletin: Prescription Drugs" U.S. Department of Health and Human Services, NIH Pub. No. 05-0580; http://archives.drugabuse.gov/prescripalert/; Passik SD, Kirsh KL, Donaghy KB, Portenoy RK (2006) "Pain and aberrant drug-related behaviors in medically ill patients with and without histories of substance abuse" Clin J Pain 22(2):173–181.7.

20. (2013) "The NSDUH Report: Nonmedical Use of Prescription-Type Drugs, by County Type" Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, April 11.

21. White AG, Birnbaum HG, Mareva MN, Daher M, Vallow S, Schein J, Katz N.J (2005) "Direct costs of opioid abuse in an insured population in the United States" Manag Care Pharm Jul-Aug;11(6):469-79; http://www.ncbi.nlm.nih.gov/pubmed/15998164.

22. Birnbaum, Howard G., White, Alan G., Schiller, M., Waldman, T., Cleveland, JM, Roland, CL (2011) "Societal costs of prescription opioid abuse, dependence, and misuse in the United States" Pain Med 2011 Apr;12(4):657-67; http://www.ncbi.nlm.nih.gov/pubmed/21392250.

23. Strassels, Scott A. (2009) "Economic Burden of Prescription Opioid Misuse and Abuse" J Manag Care Pharm 2009; 15(7):556-62; http://www.asam.org/docs/advocacy/jmcpecoburdofopioidabuse.pdf?sfvrsn=0.

24. Ibid.

25. Strassels, Scott A. (2009) "Economic Burden of Prescription Opioid Misuse and Abuse" J Manag Care Pharm 2009; 15(7):556-62; http://www.asam.org/docs/advocacy/jmcpecoburdofopioidabuse.pdf?sfvrsn=0.

26. Studies discussing these strategies include: (2013) "Guidance for Industry Abuse-Deterrent Opioids — Evaluation and Labeling" FDA Draft Guidance, January; http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf; Strassels, Scott A. (2009) "Economic Burden of Prescription Opioid Misuse and Abuse" J Manag Care Pharm 2009; 15(7):556-62; http://www.asam.org/docs/advocacy/jmcpecoburdofopioidabuse.pdf?sfvrsn=0; Hahn, Kathryn L. (2011) "Strategies to Prevent Opioid Misuse, Abuse, and Diversion That May Also Reduce the Associated Costs" Am Health Drug Benefits, 4(2):107-114.

27. "Perspectives on Opioid Analgesics for Pain Management: Optimizing the benefits while minimizing the risks" Tufts Health Care Institute Program on Opioid Risk Management, Tufts School of Medicine.

28. Hahn, Kathryn L. (2011) "Strategies to Prevent Opioid Misuse, Abuse, and Diversion That May Also Reduce the Associated Costs" Am Health Drug Benefits, 4(2):107-114.

29. Larochelle, Marc R. Zhang, Fang, Ross-Degnan, Dennis, and Wharam J. Frank (2015) "Rates of Opioid Dispensing and Overdose After Introduction of Abuse-Deterrent Extended-Release Oxycodone and Withdrawal of Propoxyphene" JAMA Internal Medicine, June; 75(6):978-987; http://archinte.jamanetwork.com/article.aspx?articleid=2276923.

30. Rossiter, Louis F., Kirson, Noam Y., Shei, Amie, White, Alan G., Birnbaum, Howard G., Ben-Joseph, Rami, Michna, Edward (2014) "Medical cost savings associated with an extended-release opioid with abuse-deterrent technology in the US" Journal of Medical Economics Vol. 17, No. 4, 2014, 279–287.

31. Ibid.

32. Ibid. Rossiter et al. found that the impact on Medicare eligible patients was not statistically significant, which they attribute to the fact that the opioid abuse problem is significantly lower in the Medicare-eligible population.

33. Rossiter, Louis F., Kirson, Noam Y., Shei, Amie, White, Alan G., Birnbaum, Howard G., Ben-Joseph, Rami, Michna, Edward (2014) "Medical cost savings associated with an extended-release opioid with abuse-deterrent technology in the US" Journal of Medical Economics Vol. 17, No. 4, 2014, 279–287.

34. Kirson, Noam Y, Shei, Amie, White, Alan G., Birnbaum, Howard G., Ben-Joseph, Rami, Rossiter, Louis F., Michna, Edward (2014) "Societal Economic Benefits Associated with an Extended-Release Opioid with Abuse-Deterrent Technology in the United States" Pain Medicine; 15: 1450–1454.

35. Ibid.

36. It should be noted that the benefits from reducing opioid abuse and diversion could be offset should opioid abusers switch to other illicit drugs. Alternatively, to the extent that opioids are a gateway drug to other illicit drugs, the reduction in opioid abuse would be amplified by a reduction in the abuse of these other illicit drugs. While these considerations are important, the lack of data availability precludes their inclusion in this review.

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