

2014

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Recommended Citation

Kirson, N. Y., Shei, A., White, A. G., Birnbaum, H. G., Ben-Joseph, R., Rossiter, L. F., & Michna, E. (2014). Societal economic benefits associated with an extended-release opioid with abuse-deterrent technology in the United States. *Pain Medicine*, 15(9), 1450-1454.

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PROFESSIONALISM & COMMENTARY

Societal Economic Benefits Associated with an Extended-Release Opioid with Abuse-Deterrent Technology in the United States

Disclosure: This study was funded by Purdue Pharma L.P. Dr. Ben-Joseph is an employee of Purdue Pharma L.P.; Drs. Kirson, Shei, White, and Birnbaum are employees of Analysis Group, Inc., a consulting firm that received funding for this research from Purdue Pharma L.P. Prof. Rossiter and Dr. Michna are consultants on this project and received funding from Analysis Group.

Common chronic pain conditions affect approximately 100 million U.S. adults and result in costs of \$560–635 billion annually in direct medical treatment costs and lost productivity [1]. In addition, pain is a common cause of disability in the United States [2]. The Food and Drug Administration (FDA) has noted that prescription opioids (RxOs) are an important component of modern pain management [3]. At the same time, the agency has acknowledged that RxO abuse is a serious public health problem. The National Survey on Drug Use and Health (NSDUH) reported that 1.8 million of the U.S. population ages 12 and up had prescription painkiller abuse or dependence in 2011 [4]. In 2007, RxO abuse accounted for an estimated \$55.7 billion (US\$ 2009) in annual societal costs in the United States [5]. These costs include health care, workplace, and criminal justice costs.

Extended-release opioids (EROs) provide a longer period of drug release and can thus be taken less frequently than immediate-release opioids [6]. However, EROs can be manipulated and tampered with in an attempt to overcome their extended-release properties. Because of their higher drug dosages, EROs may be more attractive to some abusers than immediate-release formulations [7]. Manufacturers of EROs have attempted to address the problem of RxO abuse by developing formulations with abuse-deterrent properties. For example, reformulated extended-release oxycodone HCl with abuse-deterrent technology (reformulated ER oxycodone) was introduced in August 2010 and replaced the original formulation of ER oxycodone without abuse-deterrent technology. Several studies have examined the impact of reformulated ER oxycodone among abusers. A study on the attractiveness of reformulated ER oxycodone relative to other opioid formulations among recreational opioid abusers found that reformulated ER oxycodone was rated the least attractive, least valuable, least desirable, and least likely to be tampered with among all the nonhypothetical opioid

products studied [8]. Another study of individuals being treated for substance abuse found that abuse rates of reformulated ER oxycodone were lower than historical abuse for the original formulation of ER oxycodone [9].

In terms of the economic impact of reformulated ER oxycodone, a recent paper by Rossiter et al. estimated the impact of reformulated ER oxycodone by analyzing real-world data following the introduction of reformulated ER oxycodone [10]. Although there are other RxOs on the market that use technologies designed to deter abuse, the study focused on the launch of reformulated ER oxycodone as it has gained substantial market share and is currently the only RxO that has obtained FDA approval with abuse-deterrent labeling [11]. The authors analyzed de-identified administrative claims databases covering over 56 million commercially insured beneficiaries and approximately 31 million Medicaid enrollees [12] and reported annual medical cost savings of \$430 million (US\$ 2011) associated with reformulated ER oxycodone in the United States [10].

These medical cost savings reported in Rossiter et al. are an underestimate of the full societal economic benefits of reformulated ER oxycodone, as RxO abuse is also associated with higher rates of medical resource utilization and costs among caregivers [13] and substantial workplace and criminal justice costs [5]. Reformulated ER oxycodone may reduce those abuse-related costs as well. Building on prior research, the purpose of this Commentary is to describe the results of an extension of the analysis reported in Rossiter et al. to estimate the total annual cost savings associated with reformulated ER oxycodone from a societal perspective, including both direct medical cost savings and indirect cost savings such as reduced caregiver burden and workplace and criminal justice costs.

Rossiter et al. [10] estimated the annual abuse-related medical cost savings of reformulated ER oxycodone by analyzing changes in rates of diagnosed opioid abuse associated with the introduction of reformulated ER oxycodone and calculating the excess medical costs of diagnosed opioid abuse in patient-level pharmacy and medical claims data. The findings of their claims data analyses were extrapolated to account for undiagnosed abuse and to estimate annual medical cost savings at the

U.S. population level. The study did not include estimates of the indirect cost savings of reformulated ER oxycodone, as such cost components are typically not directly observable in claims data.

For the purposes of our calculations reported here, we assumed that reformulated ER oxycodone would have the same proportional effect on abuse-related indirect costs as on abuse-related medical costs. We calculated the percent reduction in abuse-related medical costs associated with reformulated ER oxycodone and applied this same relative reduction to other cost components reported in the literature to estimate the indirect cost savings associated with reformulated ER oxycodone. The percent reduction in abuse-related medical costs was calculated by dividing the abuse-related medical cost savings of reformulated ER oxycodone from Rossiter et al. [10] by the excess medical and drug costs for opioid abuse patients from Birnbaum et al. [5], which were adjusted from US\$ 2009 to US\$ 2011 using the Consumer Price Index (CPI). The CPI increased from 214.537 to 224.939 from 2009 to 2011 [14], representing an increase of approximately 4.8%. The \$430 million reduction in abuse-related medical costs associated with reformulated ER oxycodone amounted to 1.8% of the \$24.2 billion in excess medical and drug costs for opioid abuse patients (see Table 1).

Birnbaum et al. [5] estimated abuse-related indirect costs that included costs to the criminal justice system and workplace costs (e.g., lost earnings, medically related absenteeism, and disability claims). The authors relied upon data from a number of different publicly available secondary sources (e.g., NSDUH, the Treatment Episodes Data Set from the Substance Abuse and Mental Health Services Administration, and the Bureau of Justice Statistics) and applied either the quantity method (i.e., multiplying the number of opioid abuse patients by the cost per opioid patient) or the apportionment method (i.e., apportioning the overall costs of drug abuse based on the relative prevalence of RxO to overall drug abuse) to estimate the societal indirect costs of RxO abuse.

Of the \$58.4 billion (US\$ 2011; adjusted from \$55.7 billion [US\$ 2009]) in annual societal costs of RxO abuse in the United States, excess medical and drug costs for opioid abuse patients accounted for \$24.2 billion (41.4%), criminal justice costs accounted for \$5.4 billion (9.2%), and lost workplace productivity accounted for \$26.8 billion (45.9%) (see Table 1). Lost workplace productivity included premature death, lost wages/employment, excess medically related absenteeism costs, excess disability costs, and presenteeism costs. Additional costs included excess medical and drug costs for caregivers of opioid abuse

Table 1 Medical and indirect cost savings associated with reformulated ER oxycodone

Cost Category	Cost of RxO Abuse, Millions*	Cost Savings of Reformulated ER Oxycodone, Millions†	% Reduction in Costs Due to Reformulated ER Oxycodone	Estimated Cost Savings of Reformulated ER Oxycodone, Millions‡
	[A]	[B]	[C] = [B]/[A]	[A] × [C]
Excess medical and drug costs for opioid abuse patients, including substance abuse treatment costs	\$24,180	\$ 430		\$430
Total criminal justice costs	\$5,391			\$96
Lost workplace productivity				
Premature death	\$11,762		1.8%	\$209
Lost wages/employment	\$10,169			\$181
Excess medically related absenteeism costs	\$1,902			\$34
Excess disability costs	\$846			\$15
Presenteeism costs	\$2,143			\$38
Excess medical and drug costs for caregivers of opioid abuse patients	\$1,868			\$33
Prevention and research costs	\$161			Excluded
Total§	\$58,424			\$1,035

Notes:

* From Birnbaum et al. [5]; costs are measured in US\$ 2011 (adjusted from US\$ 2009 using CPI).

† From Rossiter et al. [10]; costs are measured in US\$ 2011.

‡ Costs are measured in US\$ 2011.

§ Figures have been rounded to the nearest million.

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patients, which accounted for \$1.9 billion (3.2%), and prevention and research costs, which accounted for \$0.2 billion (0.3%).

Our estimates suggest societal benefits from reformulated ER oxycodone. In addition to the annual abuse-related medical cost savings of \$430 million associated with reformulated ER oxycodone [10], we estimated \$96 million in cost savings to the criminal justice system (see Table 1 and Figure 1). We estimated that reformulated ER oxycodone was associated with cost savings of \$209 million for reductions in premature deaths (in terms of lost earnings), \$181 million for reductions in lost wages and employment, \$34 million for reductions in excess medically related absenteeism costs, \$15 million in reductions in excess disability costs, and \$38 million for reductions in presenteeism costs, for a total of \$476 million in workplace cost savings. Accounting for excess medical and drug costs for caregivers of opioid abuse patients resulted in additional annual cost savings of \$33 million. Together, these indirect cost savings amounted to annual societal indirect cost savings of \$605 million. In total, reformulated ER oxycodone was associated with just over \$1.0 billion in medical and indirect cost savings per year in the United States. Although Birnbaum et al. included estimates of the prevention and research costs associated with RxO abuse, we did not include prevention and research in our estimates of the societal cost savings associated with reformulated ER oxycodone. Prevention and research on RxO abuse are likely fixed costs, and spending on prevention and research may not decline with the introduction of reformulated ER oxycodone, as the RxO market is dominated by RxOs without abuse-deterrent properties. As noted above, reformulated ER oxycodone is currently the only RxO that has obtained FDA approval for abuse-deterrent labeling.

Two prior studies estimated the potential societal impact of hypothetical abuse-deterrent formulations (ADFs) of RxOs. White et al. estimated potential annual health care savings from a hypothetical ADF of \$0.6–1.6 billion (US\$ 2006) in the United States in 2006 [15], whereas Skinner estimated potential annual direct and indirect cost savings of \$0.5 billion (C\$ 2011) in Canada in 2011 [16]. Both studies relied on assumed changes in rates of opioid abuse and market share, so we consider our estimate to be a more reliable estimate, as it builds on observed real-world claims data after the introduction of reformulated ER oxycodone, rather than a hypothetical situation.

Our findings may represent a conservative estimate of the annual societal cost savings associated with reformulated ER oxycodone, as we did not attempt to account for potential reductions in abuse-related mortality due to the introduction of reformulated ER oxycodone. Our indirect costs include lost productivity due to premature deaths, but we do not estimate the economic costs of lives lost. Today, RxOs account for more overdose deaths than heroin and cocaine combined [17]. RxO abuse accounted for more than 15,500 deaths in 2009, nearly a fourfold increase compared with 1999 [18]. Further research is necessary to establish the effect of reformulated ER oxycodone on abuse-related mortality. Recent studies using an adverse event reporting database have found reductions in the number of fatal adverse events (including abuse and overdose) occurring after reformulated ER oxycodone was introduced, as compared with the original formulation of ER oxycodone without abuse-deterrent technology [19,20]. To the extent that reformulated ER oxycodone contributes to reduced mortality, the societal benefits associated with reformulated ER oxycodone could be substantially higher than those presented above. Furthermore, this study focused on the economic benefits of reformulated ER

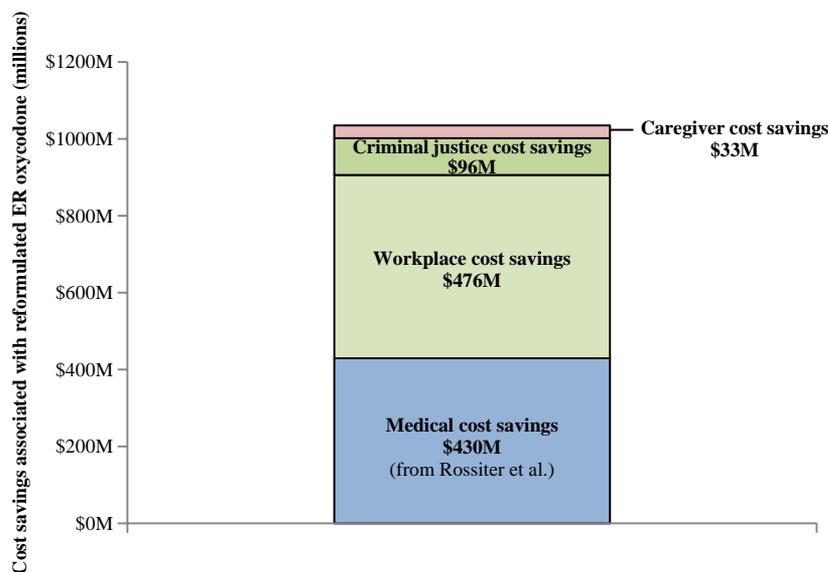


Figure 1 Total annual societal cost savings associated with reformulated ER oxycodone.

oxycodone, but there are likely additional benefits to society (e.g., decreased emotional and financial burden on family members) that are not quantified here.

As mentioned previously, this study focused on the impact of reformulated ER oxycodone as it is the only ERO that has received approval from the FDA for abuse-deterrent labeling to date [11], and it has garnered substantial market share. In the future, as new ADFs enter the market and obtain FDA approval for abuse-deterrent labeling, additional research should examine the impact of these ADFs.

Several study limitations are worth noting. This study builds on a prior study that used an observational research design, so caution is warranted in any causal interpretation of the findings. Rossiter et al. [10] observed changes in medical costs and abuse rates associated with the introduction of reformulated ER oxycodone, but it is possible that unobserved factors may have contributed to these changes. In addition, the indirect cost savings associated with reformulated ER oxycodone could not be directly observed, so we relied on the assumption that reformulated ER oxycodone had the same impact on abuse-related indirect costs as it did on abuse-related medical costs. In reality, reformulated ER oxycodone may have had a greater impact on certain cost components than on others. Although reformulated ER oxycodone has been associated with reductions in medical costs and rates of abuse, some serious abusers may switch to other substances such as RxOs without abuse-deterrent properties or illicit drugs such as heroin [21–23].

In summary, this study estimated substantial annual societal cost savings associated with reformulated ER oxycodone. Our calculations suggest that reformulated ER oxycodone was associated with annual medical cost savings of \$430 million and indirect cost savings of \$605 million, for total annual societal cost savings of approximately \$1.0 billion. Although these cost savings are sizable, they represent just 1.8% of the \$58.4 billion (US\$ 2011) in overall societal costs of RxO abuse. Over time, the societal cost savings associated with reductions in abuse could increase as more RxOs with abuse-deterrent properties are introduced. Reformulated ER oxycodone represents one tool for addressing RxO abuse, but its modest impact relative to the total societal costs of RxO abuse suggests that other initiatives, such as greater education of physicians and the identification and monitoring of patients at high-risk of abuse, will be necessary to further reduce the societal burden of RxO abuse.

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