Reduced Abuse, Therapeutic Errors, and Diversion Following Reformulation of Extended-Release Oxycodone in 2010

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Abstract: This study evaluated changes in abuse exposures, therapeutic error exposures, and diversion into illegal markets associated with brand extended-release oxycodone (ERO) following introduction of reformulated ERO. Original ERO and reformulated ERO street prices also were compared. Data from the Poison Center and Drug Diversion programs of the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS) System were used. Quarterly rates 2 years prior to introduction of reformulated ERO (October 2008 through September 2010) were compared to quarterly rates after introduction (October 2010 through March 2012) using negative binomial regression. Street prices were compared using a mixed effects linear regression model. Following reformulated ERO introduction, poison center ERO abuse exposures declined 38% (95% confidence interval [CI]: 31–45) per population and 32% (95% CI: 24–39) per unique recipients of dispensed drug. Therapeutic error exposures declined 24% (95% CI: 15–31) per population and 15% (95% CI: 6–24) per unique recipients of dispensed drug. Diversion reports declined 53% (95% CI: 41–63) per population and 50% (95% CI: 39–59) per unique recipients of dispensed drug. Declines exceeded those observed for other prescription opioids in aggregate. After its introduction, the street price of reformulated ERO was significantly lower than original ERO.

Perspective: This article indicates that the abuse, therapeutic errors, and diversion of ERO declined following the introduction of a tamper-resistant reformulation of the product. Reformulating abused prescription opioids to include tamper-resistant properties may be an effective approach to reduce abuse of such products.

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Key words: Epidemiology, extended-release oxycodone abuse, therapeutic error, diversion, reformulation.

A buse and misuse of prescription opioid analgesics is a substantial and growing public health problem. According to the 2011 National Survey on Drug Use and Health, about 1.8 million individuals met criteria for abuse or dependence of prescription pain relievers. Emergency department visits for nonmedical use of oxycodone and other pain relievers more than doubled between 2004 and 2009. Those who abuse extended-release...
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opioid medications commonly report altering the tablets by crushing (for snorting), dissolving (for injection), or chewing the medication in order to bypass the controlled-release delivery system.\textsuperscript{9,10,15} By circumventing the controlled-release mechanism, a larger quantity of active ingredient becomes available more quickly, resulting in an increased sense of euphoria and reinforcing effects. Altering tablets to use through unintended routes is associated with a higher risk of addiction.\textsuperscript{7}

OxyContin (oxycodone HCL controlled-release; Purdue Pharma LP, Stamford, CT) is one of many abused opioid analgesic products and contains extended-release oxycodone (ERO). Purdue Pharma LP reformulated the ERO tablets with physiochemical barriers to crushing and dissolving in order to deter tampering. Shipment of the original ERO by the manufacturer within the United States ceased on August 5, 2010, and shipments of reformulated ERO started on August 9, 2010. By the end of 2010, 92\% of retail prescriptions sold in the United States were for reformulated ERO. As a condition of approval, the Food and Drug Administration (FDA) required a postmarketing epidemiology program for reformulated ERO to assess whether it is less abused and misused than original ERO, particularly through nonoral routes of administration.\textsuperscript{5}

This study provides results from 2 of the postmarketing studies conducted under the epidemiology program, based on data from a sentinel surveillance system of poison centers and of drug diversion authorities.

The study uses data spanning the pre-reformulated ERO and post-reformulated ERO eras from the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS) System.\textsuperscript{5} The RADARS System programs are overseen by specialists in addiction, law enforcement, drug regulation, postmarketing surveillance, epidemiology, and statistics. RADARS System programs assess the incidence of different indicators of prescription drug misuse and abuse. This report utilizes product-specific information on abuse exposures, therapeutic error exposures, diversion, and street price from the Poison Center and Drug Diversion programs.

Four specific hypotheses about the impact of reformulated ERO following its introduction were tested:

1) Mentions of ERO among poison center abuse exposure cases would decline.
2) Mentions of ERO among therapeutic error cases would decline.
3) ERO diversion events reported by participating agencies would decline.
4) The street price of reformulated ERO would be less than the street price of the original formulation.

**Methods**

Surveillance data collected from the RADARS System Poison Center and Drug Diversion programs\textsuperscript{14} were used to estimate rates of abuse exposures, unintentional therapeutic error exposures, and diversion for ERO manufactured by Purdue Pharma LP and other opioids in aggregate in the periods before and after the introduction of reformulated ERO.

Poison centers collect data from phone calls regarding specific prescription medication exposures. These data are summarized quarterly. Information from cases classified as abuse or unintentional therapeutic errors mentioning at least 1 prescription opioid tracked by the RADARS System (ERO, buprenorphine, fentanyl, hydromorphone, methadone, oxymorphone, immediate-release oxycodone, oxymorphone, tapentadol, and tramadol) were used. Intentional abuse is defined as “an exposure resulting from the intentional improper or incorrect use of a substance where the victim was likely attempting to gain a high, euphoric effect or some other psychotropic effect.”\textsuperscript{1} Intentional therapeutic error is defined as “an unintentional deviation from a proper therapeutic regimen that results in the wrong dose, incorrect route of administration, administration to the wrong person, or administration of the wrong substance.”\textsuperscript{1}

The RADARS System Drug Diversion program obtained quarterly reports from approximately 300 drug diversion officers across all 50 states and Puerto Rico on new incidents of documented diverted drug products within their jurisdiction. An incident is one that results in a written complaint or report. Drug diversion officers represent municipal police departments, multijurisdictional drug task forces, county sheriffs’ departments, regulatory agencies (such as state medical and pharmacy boards), state police agencies, prosecutors’ offices, and departments of health. Street prices of diverted prescription opioids were examined using surveillance data from a subset of drug diversion officers (n = 125) who were selected based on consistency of reporting and geographic diversity. On a quarterly basis, standardized Street Price questionnaires were utilized, requesting information on the street values of targeted prescription opioids diverted in each jurisdiction. Price data were obtained from 787 questionnaires collected from first quarter 2010 to first quarter 2012.

Data from the Poison Center and Drug Diversion programs undergo documented quality control review by trained research staff. Longitudinal data beginning in fourth quarter 2008 collected by both programs using standard protocols were utilized.

The periods compared in this analysis were defined based on the release date of reformulated ERO. The 2 years prior to the introduction of reformulated ERO corresponding to fourth quarter 2008 through third quarter 2010 was defined as the pre-reformulated ERO period. The post-reformulated ERO period was defined to begin in the first full quarter after reformulated ERO introduction, fourth quarter 2010, and continue through first quarter 2012. Although reformulated ERO was available during the last month of third quarter 2010, the majority of prescriptions dispensed in that quarter were for original formulation ERO. In fourth quarter 2010, the majority of prescriptions dispensed were for reformulated ERO. The rates estimated for the post-reformulated ERO period included poison center exposures and drug diversion events for both original and reformulated ERO.

Abuse exposure, therapeutic error exposure, and diversion reports were summed over each drug group (ERO vs all other prescription opioids) and calendar quarter. These counts were divided by population and unique
recipients of dispensed drug (URDD), yielding a population rate and an URDD rate for each outcome, respectively.

Rates per 1,000,000 population for each quarter were based on the 2000 and 2010 U.S. Census and quantify the health-related burden of nonmedical prescription drug use. Linear interpolation was used to adjust for the 9.7% population growth observed in the United States between 2000 and 2010. Specifically, the population was estimated to increase by .24% (9.7%/(10 years × 4 quarters)) each quarter.

The URDD denominator represents the number of unique individuals who filled a prescription at pharmacies for a particular product within a quarter. These data were purchased from SDI Health by the RADARS System. Rates using URDD allow for an estimate of the magnitude of each outcome relative to a measure of contemporaneous availability of the product through legitimate drug outlets. Rates were computed per 10,000 URDD.

Two negative binomial models were fit using the log of the denominator (population and URDD) as the offset variable for each outcome of interest (abuse exposure rates, therapeutic error exposure rates, and diversion rates). For each of the outcomes, testing for differences in the mean level before and after introduction of reformulated ERO for each of the 2 drug groups (ERO and all other prescription opioids) was conducted. An interaction term was included to determine whether the declines observed for ERO were different from those observed for other opioids. Because of the low number of time points and the adjustment for overdispersion in the negative binomial regression model, the results presented do not incorporate a correction for serial correlation. However, sensitivity analyses suggest that the interpretations are robust to the inclusion of an autoregressive correlation structure. Following the initial analysis, these models were fit comparing each of the 6 quarters post-reformulated ERO introduction to the average pre-reformulated ERO rate.

In addition to the rate comparisons presented above, the street price per milligram of original formulation ERO post-reformulated ERO introduction was compared to the street price per milligram of reformulated ERO after its introduction using a mixed effects linear regression model. Prices were log-transformed to approximate a Gaussian distribution. A total of 373 reports were used. An exchangeable correlation structure was imposed within reporting agencies and drug formulation to account for correlations among street price reports.

Analyses were conducted using SAS version 9.3 (SAS Institute Inc, Cary, NC). The RADARS System Poison Center Program protocol was approved by the Colorado Multiple Institutional Review Board and by the institutional review board (IRB) of each participating poison center. A waiver of informed consent was granted for this study. The protocol for the RADARS System Drug Diversion program was reviewed by the Nova Southeastern University IRB and was granted exempt status because human subjects are not involved. The participation of coauthors from Johns Hopkins Bloomberg School of Public Health also was granted exempt status by the institution’s IRB.

Results

Table 1 presents the percentage of the U.S. population covered by the Poison Center program each quarter during the study period. The total number of abuse and therapeutic error cases mentioning either ERO or

<table>
<thead>
<tr>
<th>TIME PERIOD</th>
<th>QUARTER</th>
<th>COVERED POPULATION</th>
<th>PERCENTAGE OF POPULATION</th>
<th>ERO EVENTS</th>
<th>OTHER PRESCRIPTION OPIOIDS EVENTS</th>
<th>ERO EVENTS</th>
<th>OTHER PRESCRIPTION OPIOIDS EVENTS</th>
</tr>
</thead>
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<tr>
<td>Pre-reformulated ERO</td>
<td>2008-Q4</td>
<td>259,230,574</td>
<td>85.1</td>
<td>158</td>
<td>1,497</td>
<td>199</td>
<td>2,391</td>
</tr>
<tr>
<td></td>
<td>2009-Q1</td>
<td>259,811,325</td>
<td>85.1</td>
<td>129</td>
<td>1,314</td>
<td>134</td>
<td>2,064</td>
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<tr>
<td></td>
<td>2009-Q2</td>
<td>260,392,076</td>
<td>85.1</td>
<td>163</td>
<td>1,443</td>
<td>165</td>
<td>2,246</td>
</tr>
<tr>
<td></td>
<td>2009-Q3</td>
<td>260,972,828</td>
<td>85.1</td>
<td>164</td>
<td>1,447</td>
<td>176</td>
<td>2,384</td>
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<tr>
<td></td>
<td>2009-Q4</td>
<td>261,553,579</td>
<td>85.1</td>
<td>132</td>
<td>1,334</td>
<td>161</td>
<td>2,359</td>
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<td></td>
<td>2010-Q1</td>
<td>262,134,330</td>
<td>85.1</td>
<td>145</td>
<td>1,435</td>
<td>200</td>
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<tr>
<td></td>
<td>2010-Q2</td>
<td>264,170,953</td>
<td>85.6</td>
<td>132</td>
<td>1,334</td>
<td>177</td>
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<td>2010-Q3</td>
<td>264,754,922</td>
<td>85.6</td>
<td>183</td>
<td>1,588</td>
<td>180</td>
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<tr>
<td>Post-reformulated ERO</td>
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<td>265,338,892</td>
<td>85.6</td>
<td>101</td>
<td>1,353</td>
<td>154</td>
<td>2,401</td>
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<td></td>
<td>2011-Q1</td>
<td>267,082,225</td>
<td>85.9</td>
<td>123</td>
<td>1,622</td>
<td>135</td>
<td>2,580</td>
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<tr>
<td></td>
<td>2011-Q2</td>
<td>267,668,741</td>
<td>85.9</td>
<td>102</td>
<td>1,464</td>
<td>141</td>
<td>2,263</td>
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<tr>
<td></td>
<td>2011-Q3</td>
<td>279,924,538</td>
<td>89.7</td>
<td>90</td>
<td>1,601</td>
<td>129</td>
<td>2,276</td>
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<td>2011-Q4</td>
<td>280,536,567</td>
<td>89.7</td>
<td>92</td>
<td>1,561</td>
<td>143</td>
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<td>2012-Q1</td>
<td>282,303,059</td>
<td>90.0</td>
<td>79</td>
<td>1,610</td>
<td>132</td>
<td>2,720</td>
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*Adjusted for growth in the population as recorded by the United States Census in 2000 and 2010.
†Includes immediate-release oxycodone products, hydromorphone, fentanyl, oxymorphone, methadone, buprenorphine, tramadol, and tapentadol.
another prescription opioid are displayed by period and quarter. All quarters in the post-reformulated ERO period had fewer ERO abuse exposure mentions (range: 79–123) than quarters in the pre-reformulated ERO period (range: 129–183). In addition, there was a decline in the number of unintentional therapeutic error cases mentioning ERO from the pre-reformulated ERO period (range: 134–200) to the post-reformulated ERO period (range: 129–154). Mentions of other prescription opioids among abuse and unintentional therapeutic error cases remained relatively stable during the study period.

Fig 1 displays quarterly ERO intentional abuse rates per 1,000,000 population in panel A and per 10,000 URDD in panel B. Quarterly intentional abuse rates for other prescription opioids per 1,000,000 population are displayed in panel C and per 10,000 URDD in panel D. Predicted values and P values from the negative binomial regression models comparing the average pre-reformulated ERO rates to the average post-reformulated ERO rates also are displayed. The average ERO abuse exposure rate of .36 per 1,000,000 population in the post-reformulated ERO period was 38% (95% CI: 31–45, P < .001) less than the average rate of .58 per 1,000,000 population in the period before introduction of reformulated ERO. Similarly, the average ERO abuse exposure URDD rate in the post-reformulated ERO period (1.53 per 10,000 URDD) declined by 32% (95% CI: 24–39, P < .001) from the pre-reformulated ERO average (2.23 per 10,000 URDD). The average abuse exposure population rates for other prescription opioids before and after introduction of reformulated ERO were not significantly different. However, the average URDD rate for other prescription opioids in the period following the introduction of reformulated ERO declined by 9% (95% CI: 3–14, P = .002). The interaction term in both models was significant (P < .001), indicating that the

Figure 1. Poison center intentional abuse exposure rates per 1,000,000 population (A) and 10,000 URDD (B) for ERO and other prescription opioids (C, D) from fourth quarter 2008 through first quarter 2012.
declines in ERO population and URDD abuse exposure rates were greater than the changes observed for other prescription opioids.

In all 6 quarters post-reformulated ERO introduction, the ERO abuse exposure population rate was significantly less than the average pre-reformulated ERO rate. The magnitude of the decline ranged from a 21% decline in first quarter 2011 to a 52% decline in first quarter 2012. In 5 of the 6 quarters, the URDD rate was significantly less than the pre-reformulated ERO introduction average rate. Declines ranged from a 17% decline in first quarter 2011 to a 39% decline in first quarter 2012.

Fig 2 displays quarterly ERO therapeutic error rates per 1,000,000 population in panel A and per 10,000 URDD in panel B. Quarterly therapeutic error rates for other prescription opioids per 1,000,000 population are displayed in panel C and per 10,000 URDD in panel D. The average ERO population rate declined by 24% (95% CI: 15–31, \(P < .001\)), and the average ERO URDD rate declined by 15% (95% CI: 6–24, \(P = .002\)). The decline in the average ERO therapeutic error population rate following introduction of reformulated ERO was significantly greater than the change observed for other prescription opioids (\(P < .001\)). Although the magnitude of decline in URDD rates was larger for ERO than other opioids (15 vs 8%), the interaction term comparing these declines did not indicate a statistically significant difference (\(P = .219\)).

In 5 of the 6 quarters post-reformulated ERO introduction, the therapeutic error population rate for ERO was significantly less than the average pre-reformulated ERO population rate. Declines ranged from 13% in fourth quarter 2010 to 31% in third quarter 2011. In 2 of the 6 quarters post-reformulated ERO, the URDD rate was significantly lower than the pre-reformulated ERO introduction average.

Table 2 shows the portion of the U.S. population covered by the Drug Diversion program each quarter.
During the study period, the total number of diversion events of ERO and that of other prescription opioids also are displayed by period and quarter. The number of ERO diversion events ranged from 396 to 488 in the period before introduction of reformulated ERO and from 150 to 306 in the period after introduction of reformulated ERO. Diversion events of other prescription opioids remained relatively stable during the study period.

Fig 3 displays quarterly ERO diversion rates per 1,000,000 population in panel A and per 10,000 URDD in panel B. Quarterly diversion rates for other prescription opioids per 1,000,000 population are displayed in panel C and per 10,000 URDD in panel D. The average ERO diversion rate of 1.63 per 1,000,000 population in the post-reformulated ERO period was 53% (95% CI: 41–63, \(P < .001\)) less than the average rate of 3.47 per 1,000,000 population in the period before the introduction of reformulated ERO. Similarly, the average ERO diversion URDD rate declined by 50% (95% CI: 39–59, \(P < .001\)) following introduction of reformulated ERO. The change in ERO rates from the pre- to post-reformulated ERO period were significantly \(P < .001\) greater than the change observed for the other prescription opioids for both population- and URDD-based denominators.

The ERO diversion population rate in 5 of the 6 quarters post-reformulated ERO introduction was significantly less than the pre-reformulated ERO introduction average. Declines ranged from 21% in fourth quarter 2010 to 69% in third quarter 2011. In 5 of the 6 quarters post-reformulated ERO introduction, the URDD rate was significantly less than the pre-reformulated ERO introduction average. Declines ranged from a 21% decline in fourth quarter 2010 to a 66% decline in third quarter 2011.

The geometric mean street price for reformulated ERO following its introduction was $.70 per mg, 22% lower (95% CI: 9–33, \(P = .002\)) than the street price of the original formulation of ERO, $.89 per mg.

Although abuse rates, diversion rates, and street price declined, the results demonstrate ERO abuse exposures and diversion persisted following introduction of the new formulation. It should be noted that for 3 of the 6 quarters post-reformulated ERO introduction in the Poison Center program and 2 of the 6 quarters in the Drug Diversion program, more than half of the ERO mentions were for the original formulation. Therefore, the results likely represent conservative estimates of the tamper-resistant benefit of the reformulated ERO.

### Discussion

Rates of ERO abuse exposures and diversion showed a significant decline following introduction of reformulated ERO. Declines in abuse exposure and diversion rates for ERO were greater than those observed for all other opioids in aggregate tracked by the RADARS System. The street price of reformulated ERO was 22% lower than the street price of the original formulation of ERO in the post-reformulated ERO introduction time period. Finally, there was a decline in unintentional therapeutic error rates involving ERO following the introduction of reformulated ERO, though the decline in the URDD rate was not significantly different from the decline observed for other opioids. The smaller decrease in URDD rates relative to population rates may be due to the decline in the number of individuals filling prescriptions following the introduction of reformulated ERO. It also may be due to the broad range of exposures classified as unintentional therapeutic error, beyond administration through incorrect routes. Overall, the declines observed across multiple indicators support the effectiveness of reformulated ERO in reducing abuse, diversion, and therapeutic errors involving ERO.

The difference in rates reported here reflects a comparison of average rates across the pre- versus post-reformulated ERO time periods.
post-reformulated ERO periods. However, for most outcomes, the rates decreased progressively through the post-reformulated ERO period. Therefore, the differences in average rates over the entire post-reformulated ERO period are smaller than those for more recent quarters when compared to the pre-reformulated ERO period. In addition, a large proportion of ERO exposures in the post-reformulated ERO period include poison center exposures and drug diversion events for the original formulation. As a result, the declines in rates reported here are conservative estimates of the impact of reformulated ERO formulation. The results in this study indicate a reduction in street price of reformulated ER oxycodone (ERO) relative to that of the original ERO, which is considerably smaller than the reduction in diversion events after the reformulation was introduced. It is not clear exactly why this is, but it could indicate that there is a threshold price below which drug dealers no longer carry drugs (what economists refer to as an inelastic price), so that the volume of sales fall more precipitously than the price.

The current study has notable limitations. Poison center cases are dependent on voluntary reporting of exposures and diversion cases are based on participating agency responses, leading to potential selection biases. These surveillance methods likely underestimate the true quarterly incidence of these events. However, the stability of the methodology in both programs over time and across products would suggest that estimates of changes over time are accurate. In addition, it is unlikely that this bias would be differential based on time period or on drug product, especially because the rates of exposures for both ERO and the comparator of all other prescription opioids were relatively stable in the several quarters preceding introduction of reformulated ERO.

Another limitation of the study is the potential for misclassification of product information by poison center staff or law enforcement agents. However, both
programs implement thorough quality control procedures that were in place across the entire study period. Also, in the Drug Diversion program, seized drugs often are available to confirm product identification. This reduces the potential for bias in the risk estimates. The current study did not adjust for other interventions that were implemented during the study period. These may include prescription drug monitoring programs or other regional programs intended to reduce prescription drug abuse. Although this is a limitation, the magnitude of the differences between changes in ERO rates and changes in other prescription opioids indicates that declines in ERO rates following introduction of reformulated ERO can be attributed to the introduction of reformulated ERO. This study did not examine differences within strata of gender, ethnicity, age, or amount of substance administered because not all programs included collect the requisite data. Examining such differences will require further inquiry. However, the gender, ethnicity, and age characteristics of the source population did not differ substantially in the pre and post periods and, therefore, are unlikely to have influenced the overall findings. Overall, this supports the effectiveness of the reformulation of ERO to reduce abuse and diversion.

The current study has notable strengths. Rates were calculated per URDD, demonstrating that decreases in rates cannot be entirely explained through declines in the number of prescriptions filled for reformulated ERO. The RADARS System Poison Center and Drug Diversion programs combined cover more than 90% of the U.S. population, indicating that the results are generalizable to the entire U.S. population.

In summary, the results suggest that the reformulation of ERO was followed by declines in abuse exposures and diversion. In addition, reformulated ERO had a lower street price than the original formulation. Results also suggest that the new formulation may reduce mistaken use through unintended routes of administration by patients. In spite of substantial reductions, reformulated ERO is still abused and diverted. Although this study does not examine whether changes in the formulation of ERO alter patterns by which individuals abusing ERO administer the drug, results presented elsewhere suggest that both oral and parenteral (ie, injecting, snorting, and smoking) routes of administration declined following introduction of reformulated ERO, though parenteral routes showed a greater decline.

This study does not measure the success of the formulation change in reducing the overall burden of prescription opioid abuse. Recent evidence indicates that significant declines in ERO abuse were observed among new opioid-dependent treatment enrollees post-reformulated ERO introduction; however, concomitant increases in the abuse of heroin and other prescription opioids also were noted. Other substance abuse surveillance systems have not found changes in rates of heroin use after introduction of reformulated ERO but have suggested increases in the abuse of other specific prescription opioids. In contrast, the findings show an overall decline in abuse exposures and diversion of other prescription opioids analyzed in aggregate, although trends for specific opioids were not examined individually. As heroin is an illicit drug, exposures were not included in the comparator of other prescription opioids. Results observed in this study for overall prescription use patterns are consistent with slight declines of nonmedical use of prescription opioids observed in the past year by the National Survey on Drug Use and Health. To understand the extent to which the formulation changes led opioid-dependent users to substitute abuse of one opioid for another requires further research. It is also noteworthy that declines in the street price of reformulated ERO were not as substantial as those observed in diversion events. This may reflect continued demand among individuals who abuse ERO through intended routes or a minimum street price for the product. Further inquiry is needed to assess these phenomena.

The current findings indicate that tamper-resistant products may be an effective component of the President’s plan to employ a multipronged, multiagency strategy to prevent prescription drug abuse and its consequences. Given the ease with which abusers can switch to non-tamper-resistant products, it may be difficult to evaluate the potential public health impact of the new formulations unless all prescription opioids with high abuse potential, and that are preferred by opioid abusers, include effective tamper- or abuse-resistant properties. This would allow for a more definitive national test of the impact of these formulations on the morbidity and mortality associated with prescription opioids.

Acknowledgments

S.G.S. and B.B.B. had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of this data analysis.

References


