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# Tamper-Resistant Properties of Drugs Regulations (TRPDR)

## Cost Impact Analysis, 2019

PMPRB presentation to federal, provincial, and territorial public plan representatives on September 29, 2015.

Patented Medicine Prices Review Board (PMPRB)

March 24, 2016

# Background

## Tamper-Resistant Properties of Drugs Regulations

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- Health Canada published a pre-consultation notice on the proposed *Tamper-Resistant Properties of Drugs Regulations* in the *Canada Gazette, Part I*, on June 27, 2015.
  - ♦ Sought input from stakeholders and the general public, with a 45 day comment period.
- Solid oral dosage forms of controlled-release oxycodone products, where oxycodone is the only medicinal ingredient, were proposed as the first category of substances required to have tamper-resistant properties – referred in this analysis as **oxycodone CR**.
- The regulations propose a three-year coming-into-force period to provide time for product reformulation and supply chain adjustments.
- More details on the proposed regulation are available at:  
<http://www.gazette.gc.ca/rp-pr/p1/2015/2015-06-27/html/notice-avis-eng.php#ne10>

# Background

## PMPRB role

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- The Patented Medicine Prices Review Board (PMPRB) is an independent quasi-judicial body established by Parliament in 1987.
- The PMPRB has a dual role: to ensure that prices at which patentees sell their patented medicines in Canada are not excessive; and to report on pharmaceutical trends of all medicines and on R&D spending by patentees.
- The PMPRB was asked by Health Canada (Controlled Substances and Tobacco Directorate) to estimate the potential impact of the proposed regulatory change on drug expenditures at the national level, as well as for public and private plans.

# Acknowledgements

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- This analysis was prepared by the Patented Medicine Prices Review Board (PMPRB) as part of the National Prescription Drug Utilization Information System (NPDUIS).
- This analytical work was done in consultation with the NPDUIS Advisory Committee.
- The PMPRB NPDUIS staff contributed to the analytical content of the report:
  - Tanya Potashnik – Director, Policy and Economic Analysis
  - Elena Lungu – Manager, NPDUIS
  - Gary Warwick – Senior Economic Analyst
  - Karine Landry, Economic Analyst
  - Carol McKinley – Communication Advisor
  - The PMPRB scientific and editing groups

# Background

## About NPDUIS

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- NPDUIS is a research initiative established by federal, provincial, and territorial Ministers of Health in September 2001. It is a partnership between the PMPRB and the Canadian Institute for Health Information (CIHI).
- Its purpose is to provide policy makers and public drug plan managers with critical analyses of price, utilization and cost trends, so that Canada's health care system has more comprehensive and accurate information on how prescription drugs are being used and on sources of cost pressures.
- NPDUIS operates independently of the regulatory activities of the Board of the PMPRB. The statements and opinions expressed in this NPDUIS report do not represent the position of the PMPRB with respect to any regulatory matter.
- The PMPRB conducts its NPDUIS analytical reporting under the guidance of the NPDUIS Advisory Committee. The Committee advises and supports the PMPRB in establishing research priorities, in the development of research methodologies and in the interpretation of analytical results.
- The Advisory Committee is composed of representatives from public drug plans in British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, the Yukon, and Health Canada. It also includes observers from CIHI and the Canadian Agency for Drugs and Technologies in Health (CADTH).

# Outline

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- Purpose of the analysis
- Data sources
- Opioid market considered
  1. Overview of the opioid market in Canada
  2. NPDUIS public plans
  3. Considerations and assumptions for the estimations
  4. Cost impact analysis of the TRPDR
- Limitations

# Purpose of the analysis

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1. To provide a high-level overview of the opioid market in Canada that would be affected by the TRPDR.
2. To estimate the cost impact of the TRPDR on drug sales/expenditures at the national level, as well as for the three market segments:
  - Public
  - Private
  - Out-of-pocket.

# Data sources

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**1. National market: MIDAS™, IMS AG. All rights reserved.**

- Utilization and sales at manufacturer price levels for the retail sector for 2006–2014.
- Quarterly data available to Q4-2014 allowed for a detailed analysis of past trends and forecasting to 2019.

**2. Public, private and out-of-pocket markets: IMS Brogan Payer Insight**

- Breaks down the national market into the three market segments for 2013: public, private and out-of-pocket.
- Prescriptions are flagged as public, private or out-of-pocket based on who paid the largest portion of the cost.
- Assumptions of opioid market segmentation were based on this data.
- Estimates and projections of the Canadian market were based on the MIDAS database.

Although based in part on data obtained under license from the IMS Brogan Payer Insight and IMS AG's MIDAS™ Database, the statements, findings, conclusions, views and opinions expressed in this report are exclusively those of the PMPRB and are not attributable to either IMS Brogan or IMS AG.



# Data sources (cont'd)

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## 3. NPDUIS Public Plans: NPDUIS Database, Canadian Institute for Health Information (CIHI)

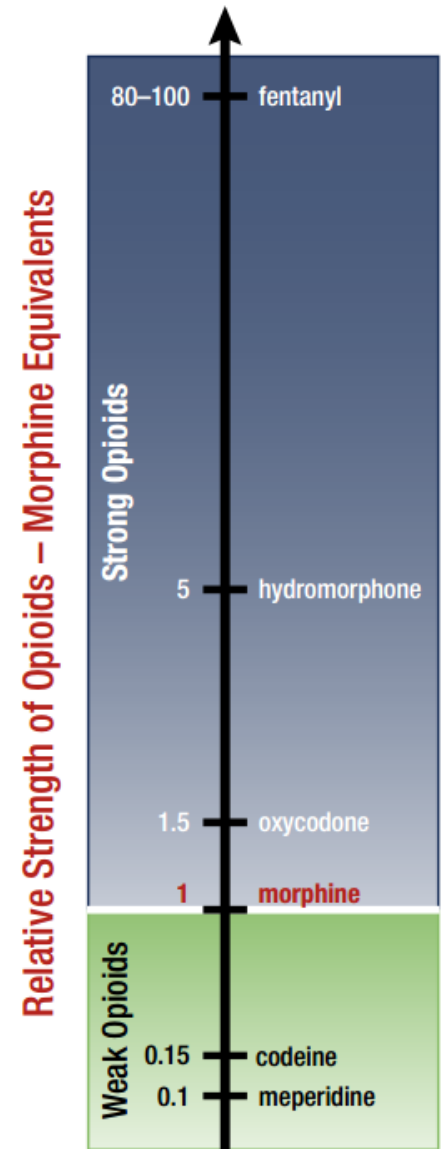
- Drug cost accepted for reimbursement by NPDUIS public drug plans for 2011/12 to 2013/14 fiscal years.
- The NPDUIS Database houses pan-Canadian information on public drug programs. It contains prescription claims-level data collected from publicly financed drug benefit programs, as well as formulary data, drug product information and information on public drug plan policies.

Parts of this material are based on data and information provided by the Canadian Institute for Health Information. However, the analyses, conclusions and/or statements expressed herein are not those of the Canadian Institute for Health Information.

# Opioid market

- The cost impact analysis focuses on the opioid drug market and considers the following drugs:

- ♦ Codeine
- ♦ Morphine
- ♦ Oxycodone
- ♦ Hydrocodone
- ♦ Hydromorphone
- ♦ Fentanyl



# Opioid market

## Oxycodone drugs considered

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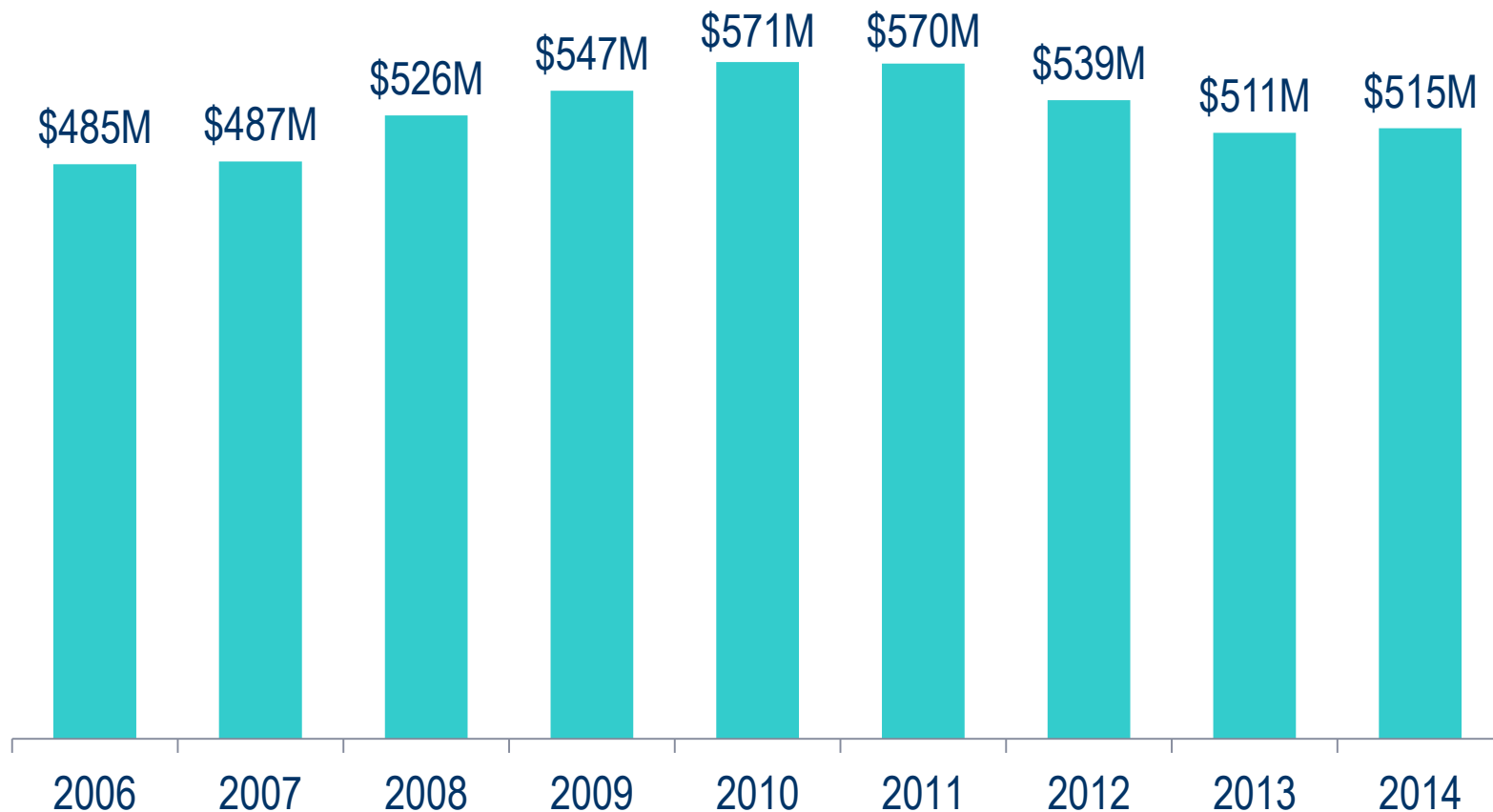
- **Oxycontin (impact of the switch to OxyNEO)**
- **OxyNEO**
- **Oxycodone CR**
  - ♦ Target of the proposed regulations: solid oral dosage forms of controlled-release oxycodone products, where oxycodone is the only medicinal ingredient.
- **Oxycodone - short acting** (Oxy.IR and other non-patented versions)
- **Oxycodone and Acetaminophen**
- **Oxycodone and ASA**
- **Oxycodone and Naloxone** (Targin)



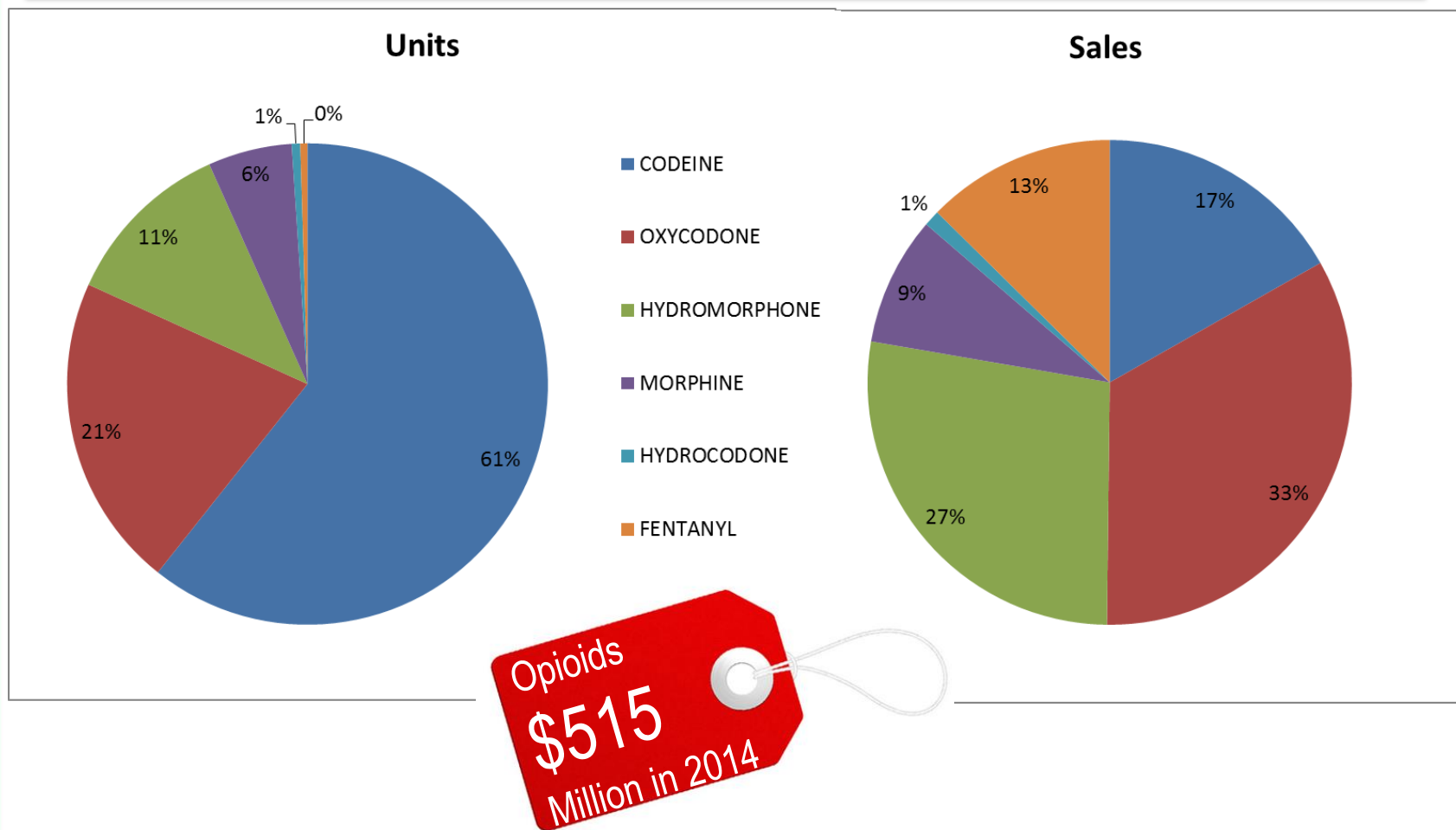
# 1. Overview of the opioid market in Canada

**A retroactive look at the status quo**

# National sales for opioids, 2006–2014



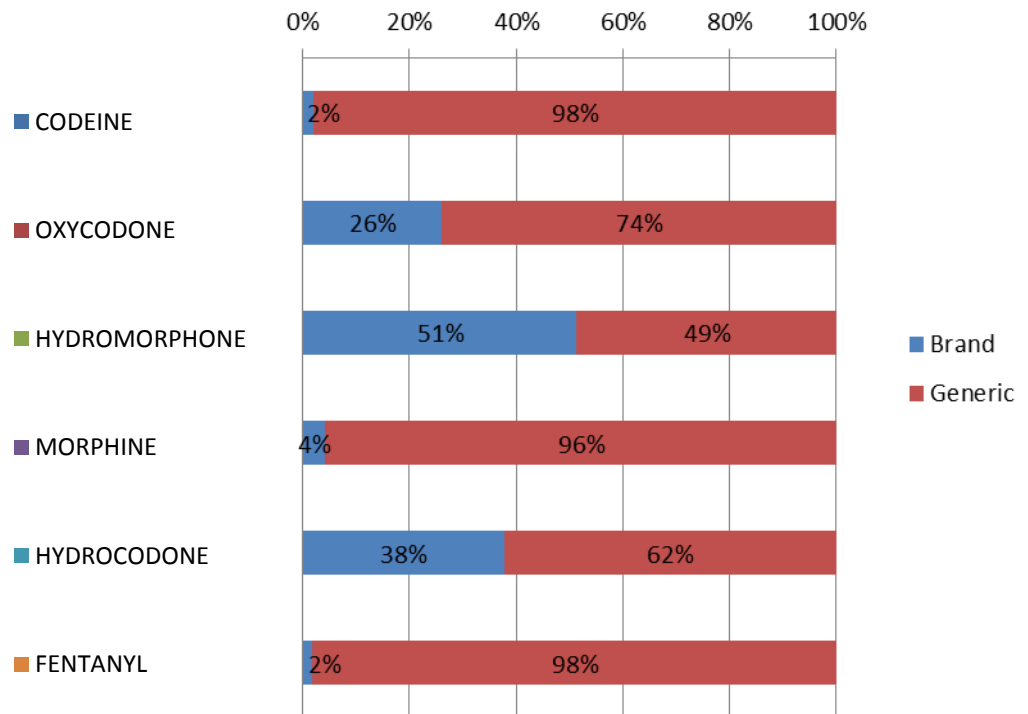
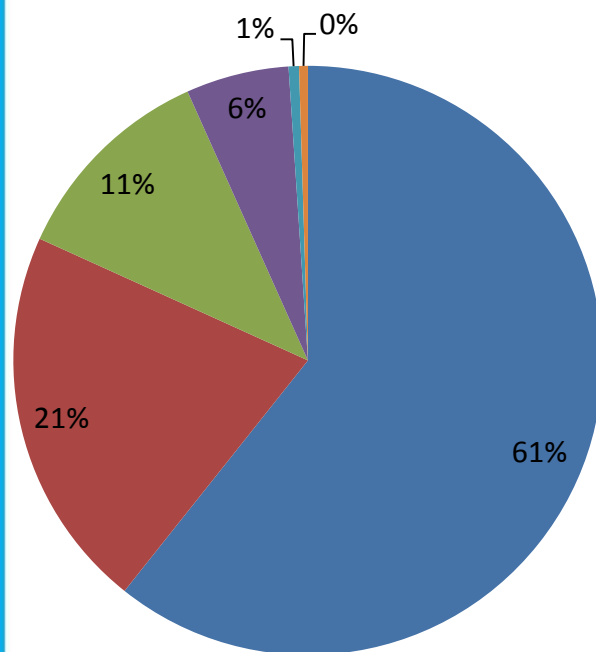
# Units and sales of opioids in Canada, 2014



# Canadian utilization of opioids, 2014

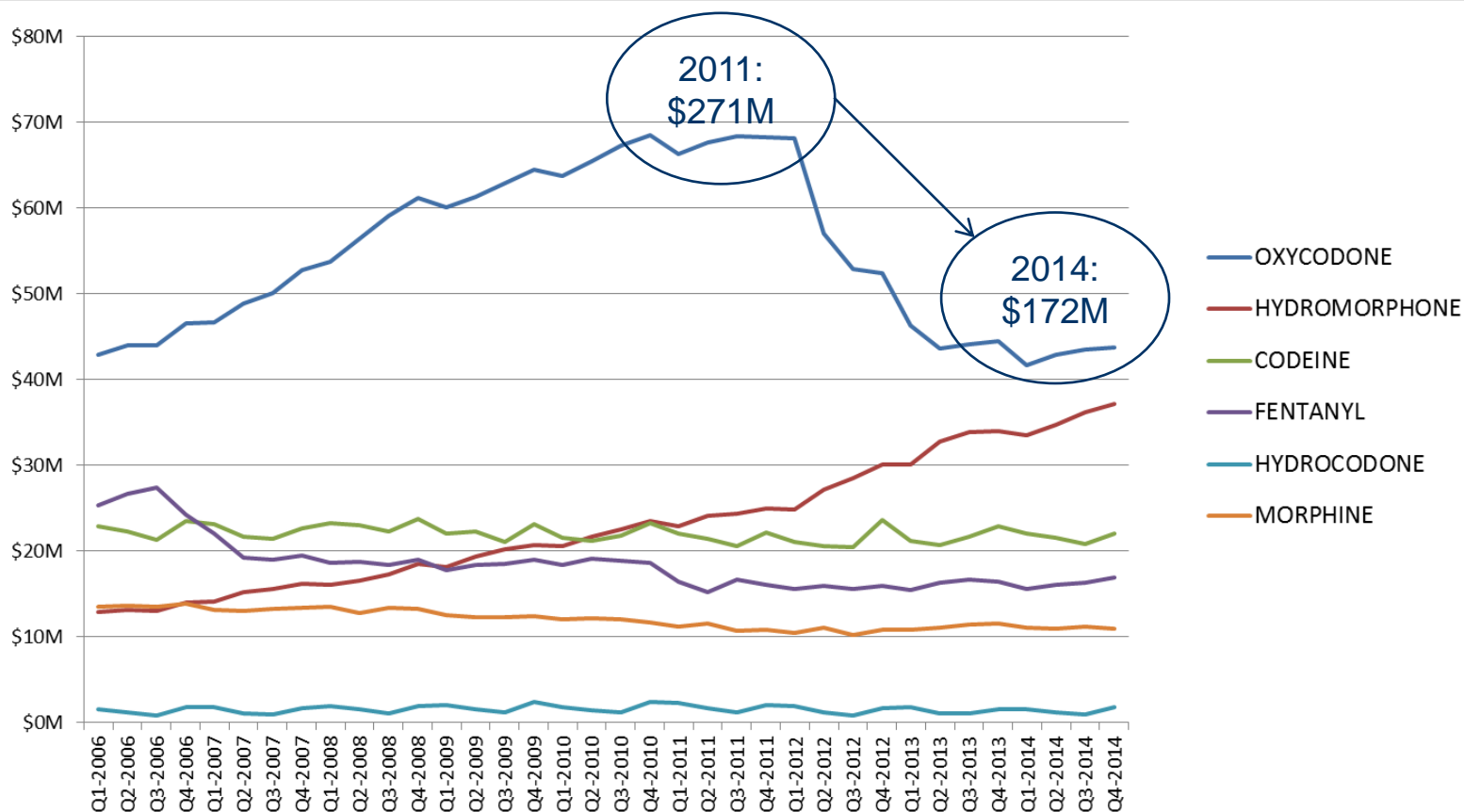
## Brand versus generic

With the exception of hydrocodone and hydromorphone, the market is primarily generic (units, 2014)



# Trends in opioid sales, 2006–2014

The drop in sales for oxycodone reflects the switch to OxyNeo and the change in provincial benefit status.

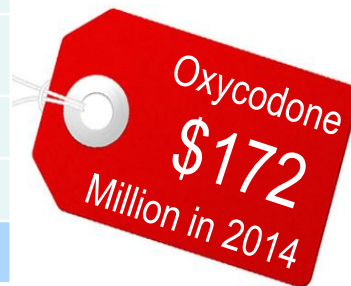




# Purdue Pharma tops the list of corporations supplying oxycodone in Canada

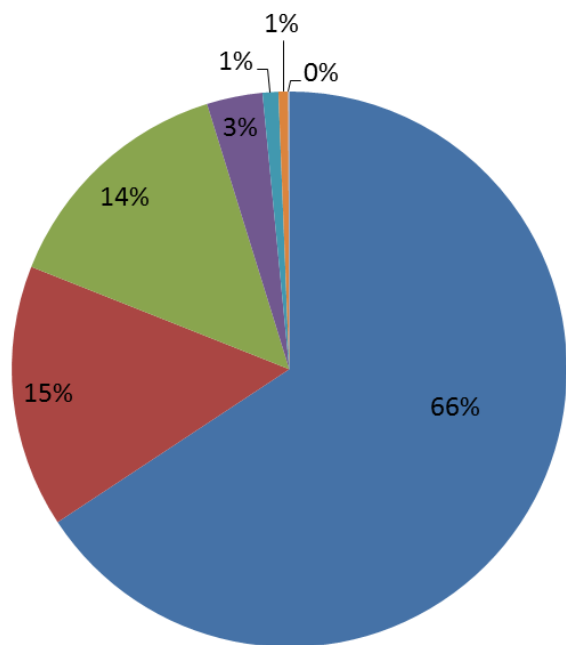
Purdue Pharma produce(d): OxyNEO, Targin, Oxy.IR and OxyContin (discontinued)

Corporations	2011	2012	2013	2014
Mundi. Int. (Purdue Pharma)	84%	81%	68%	65%
Teva	9%	10%	13%	14%
Novartis	3%	3%	4%	5%
Pharmascience (Cdn)	1%	2%	3%	5%
Apotex	0%	0%	5%	4%
Bristol-Myers Squibb	3%	3%	4%	4%
Actavis	0%	0%	1%	2%
Sanis Health Inc.	0%	1%	1%	1%
Pro Doc	0%	0%	0%	0%
Riva	0%	0%	0%	0%
TOTAL oxycodone	\$271M	\$231M	\$179M	\$172M

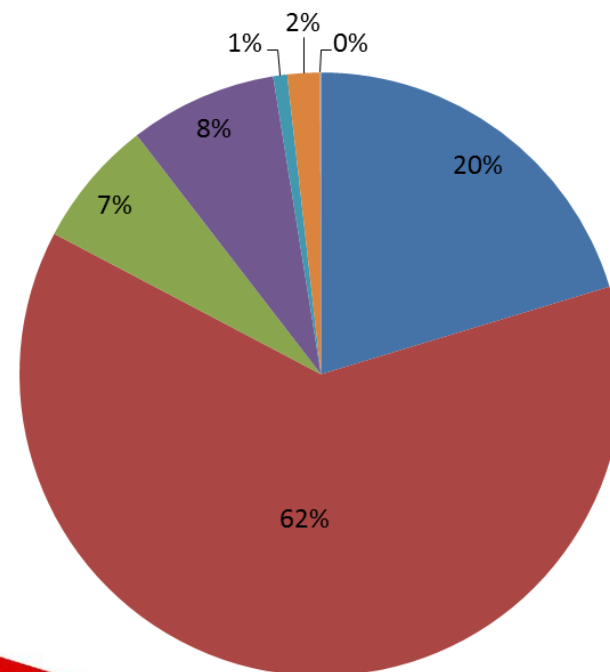


# Units and sales of oxycodone in Canada, 2014

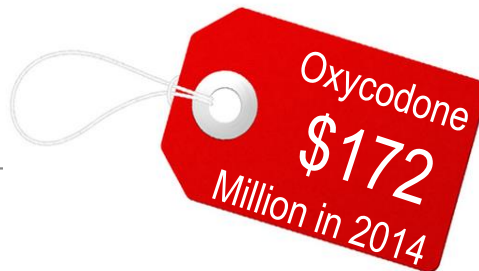
Units



Sales



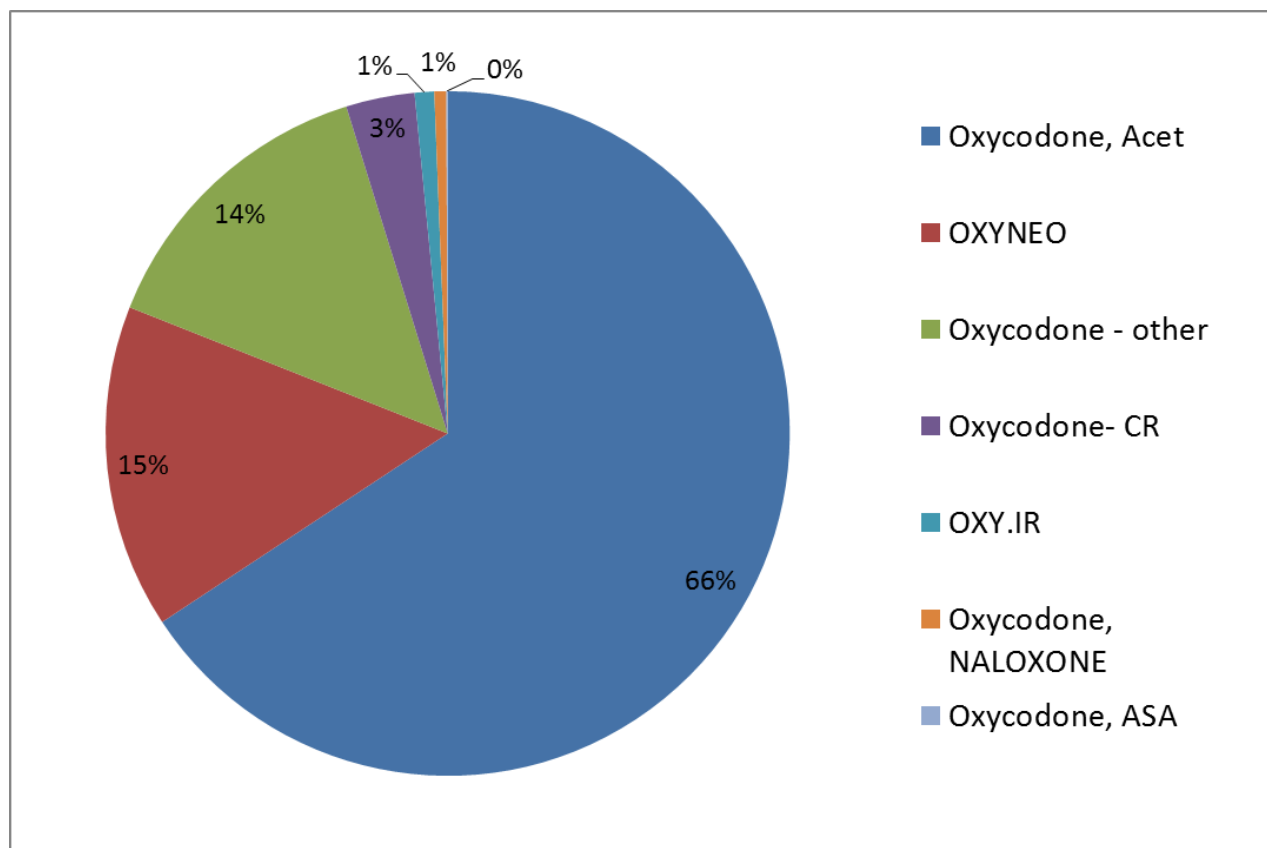
- Oxycodone, Acet
- OXYNEO
- Oxycodone - other
- Oxycodone- CR
- OXY.IR
- Oxycodone, NALOXONE
- Oxycodone, ASA



# Canadian utilization of oxycodone, 2014

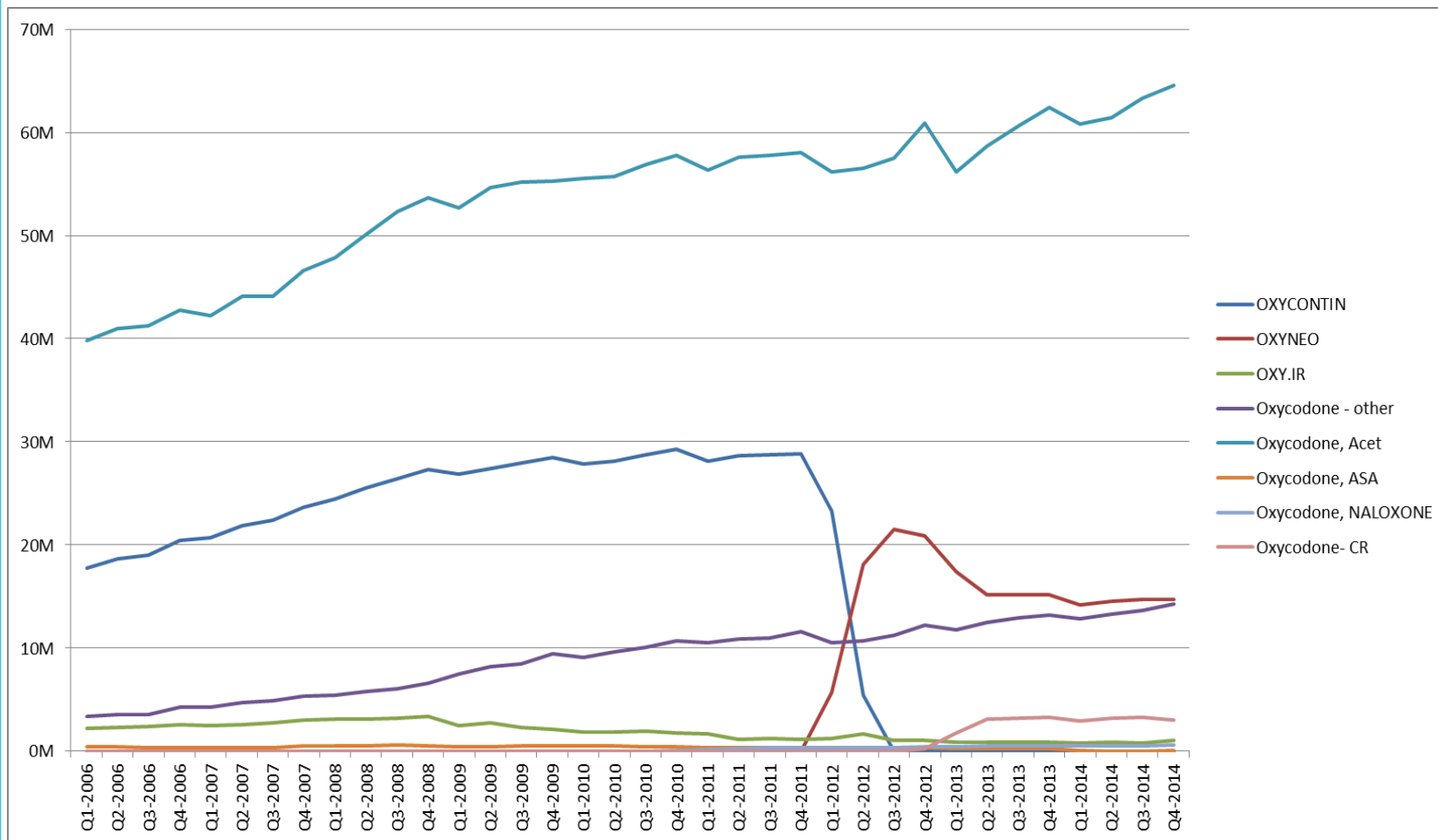
## Brand versus generic

With the exception of Purdue Pharma products (OxyNEO, Oxy.IR and Targin), the oxycodone market is primarily generic (units, 2014)



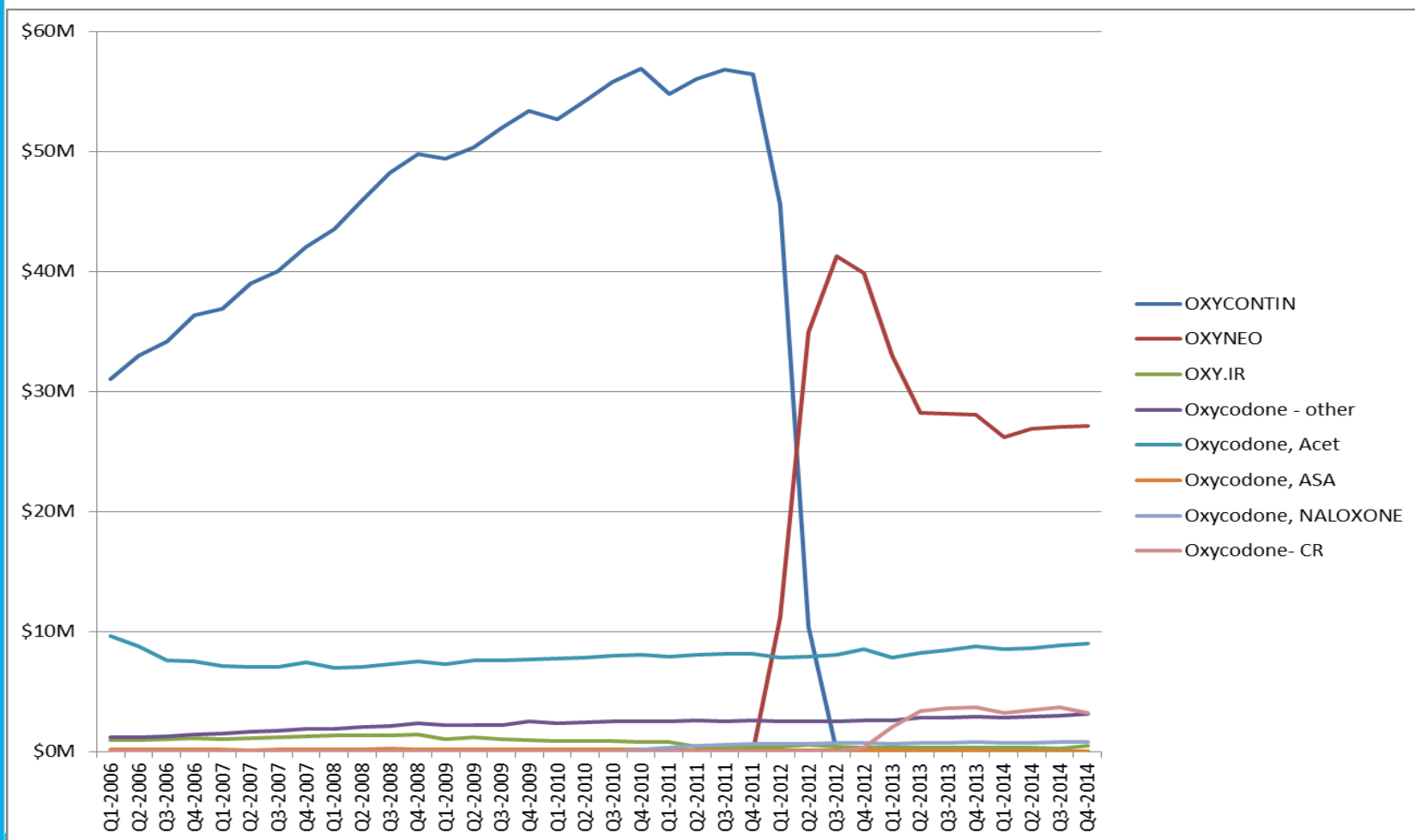
# Switch from OxyContin to OxyNEO (units)

Units sold in Canada, by type of oxycodone drug



# Switch from OxyContin to OxyNEO (sales)

## Sales in Canada, by type of oxycodone drug



Oxycodone - other: SUPEUDOL, PMS-OXYCODONE, OXYCODONE (generic)

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Source: MIDAS™, IMS AG. All rights reserved.

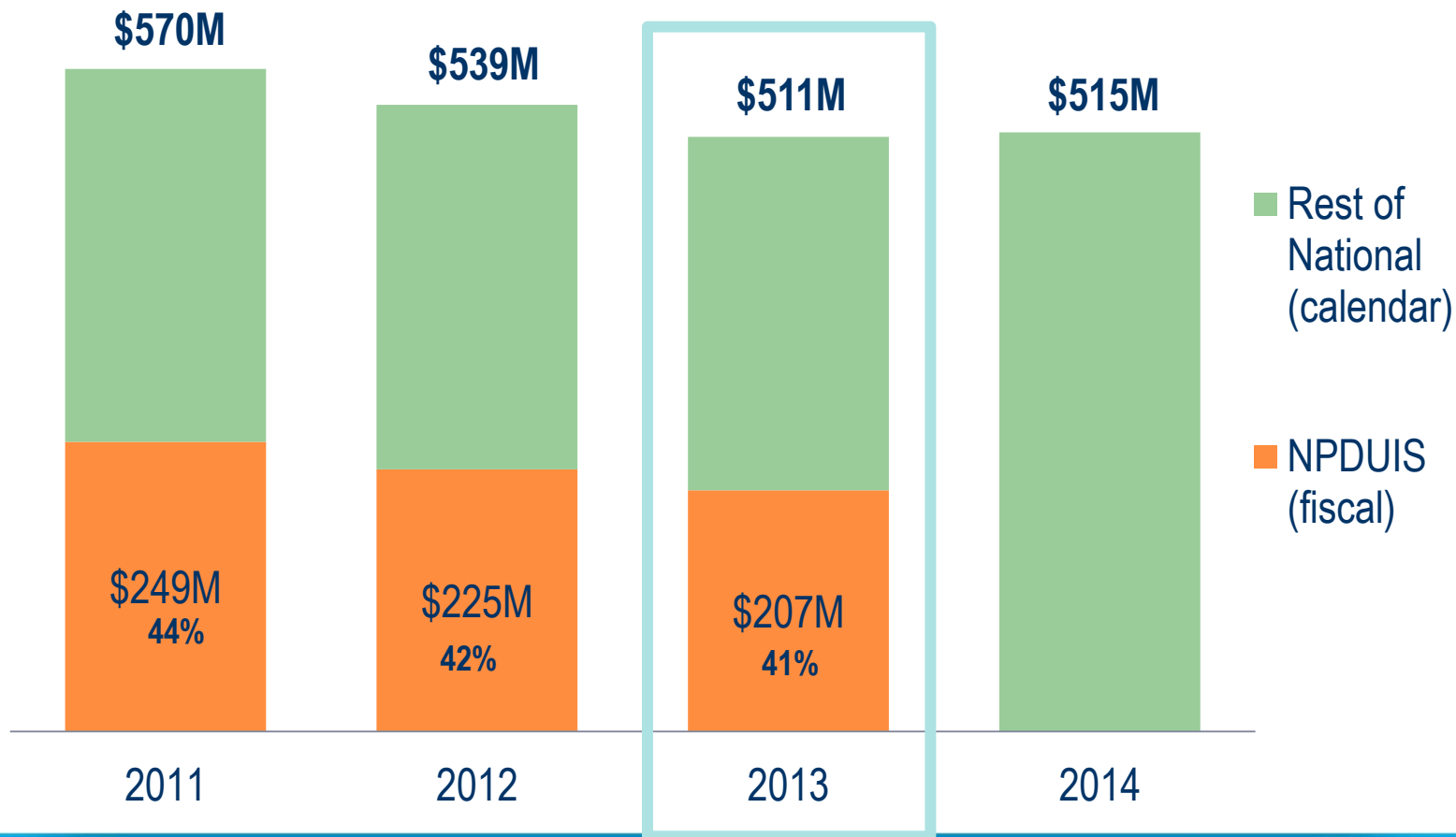


[www.pmprb-cepmb.gc.ca](http://www.pmprb-cepmb.gc.ca)

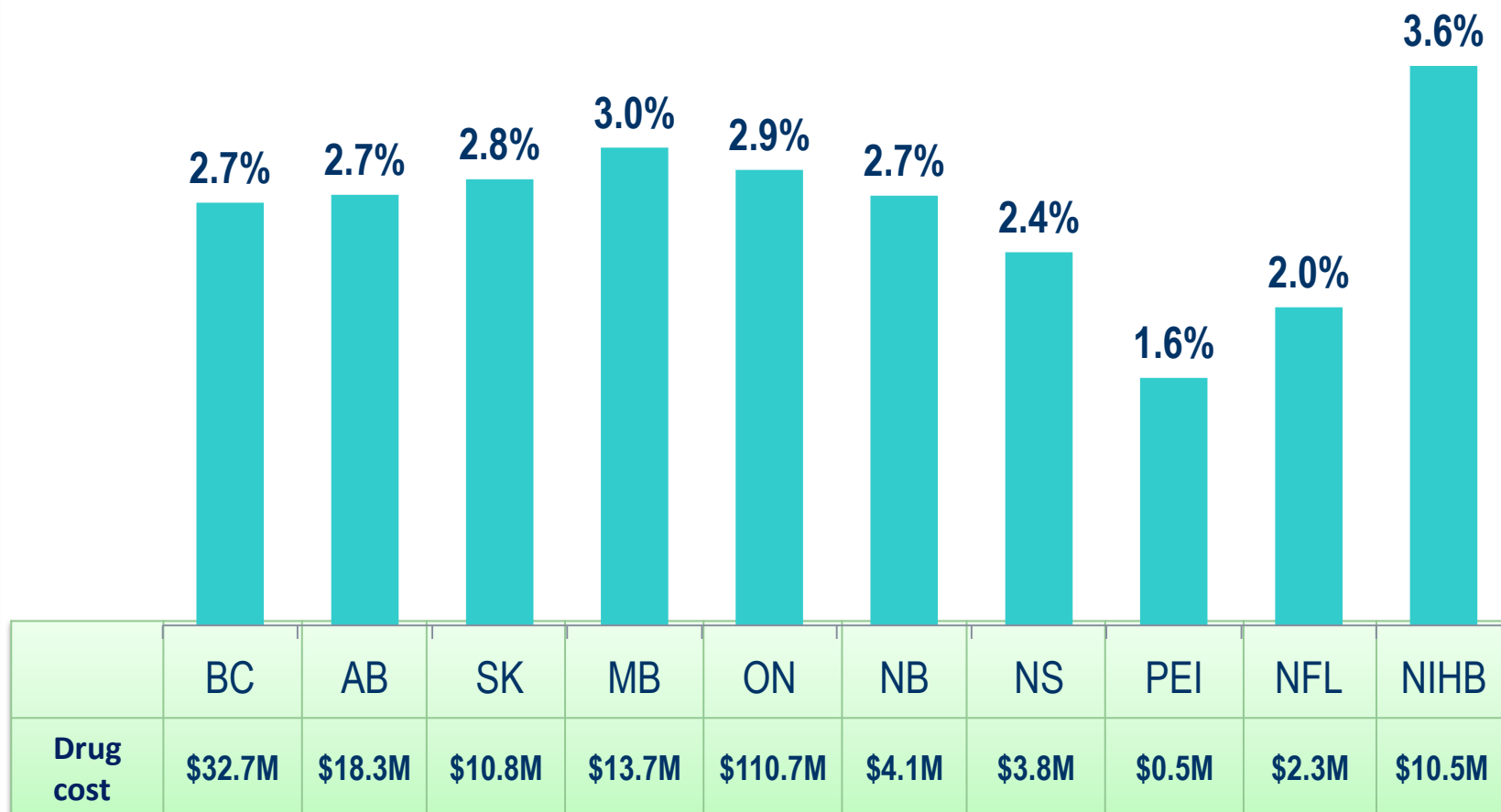
## 2. NPDUIS Public Plans

# MIDAS vs. NPDUIS database

## Drug cost in NPDUIS plans vs. national sales, opioids



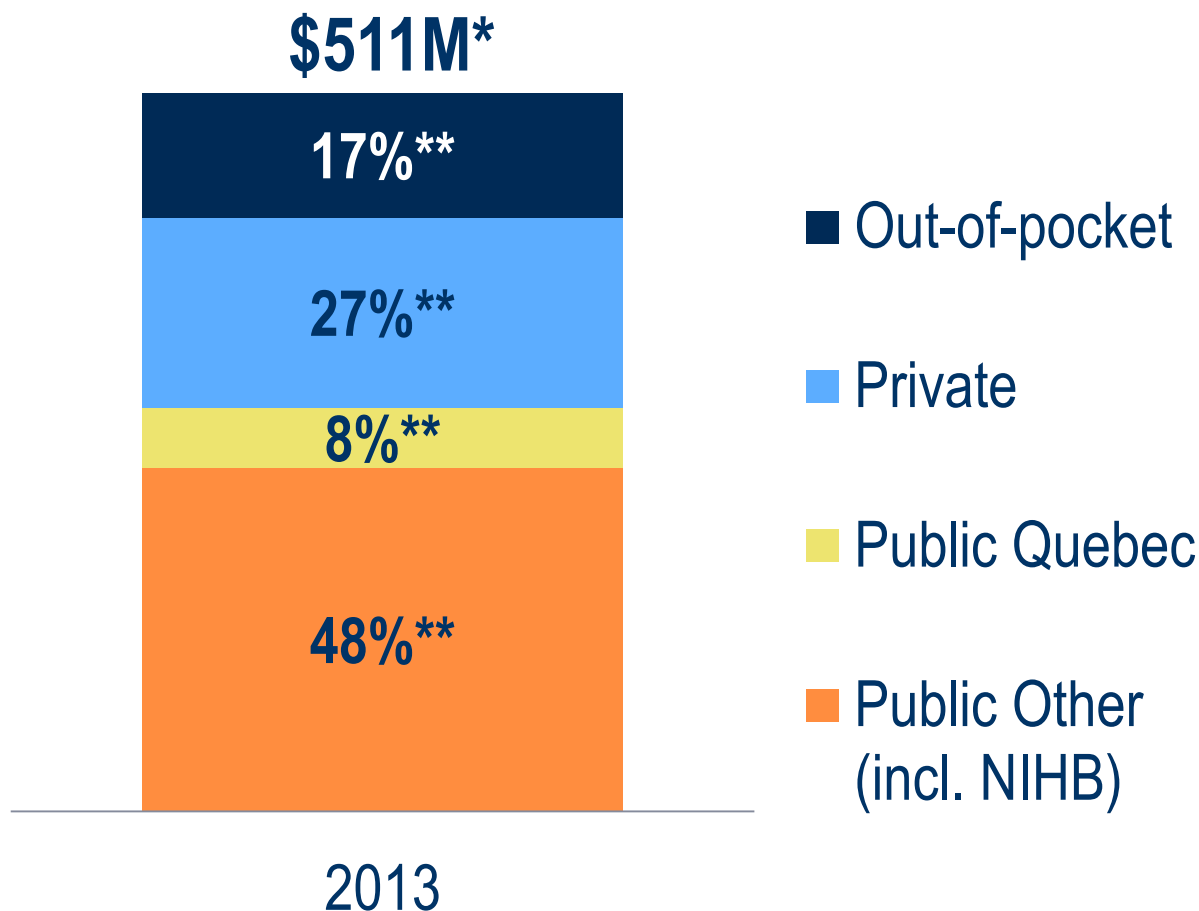
# Opioid share of cost in NPDUIS plans, 2013/14





# MIDAS and Payer Insight databases, 2013

## Opioid sales distribution by market segment



\*Source: MIDAS™, IMS AG. All rights reserved.

[www.pmprb-cepmb.gc.ca](http://www.pmprb-cepmb.gc.ca)

\*\*Source: IMS Brogan Payer Insight



### 3. Considerations for the estimated cost impact of the TRPDR

# Methodology

## Two scenarios

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- **STATUS QUO – Estimated 2019 sales assuming no TRPDR**
    - ♦ Projects the current trends assuming no tamper-resistant requirements.
  - **TRPDR – Estimated 2019 sales under the proposed regulations**
    - ♦ Assumes that the tamper-resistant requirements come into effect starting in 2019 and all solid oral dosage forms of controlled-release oxycodone products, where oxycodone is the only medicinal ingredient, will only be available in tamper-resistant form.
- **Estimated Cost Impact – 2019**
    - ♦ The difference between the TRPDR 2019 sales and the STATUS QUO 2019 sales.
    - ♦ The impact is determined by market segment: public, private and out-of-pocket.
    - ♦ The impact is reported as an absolute amount and as relative amounts for the oxycodone market, as well as an amount for the entire opioid market, in 2019.

# Methodology

## Two sensitivity analyses

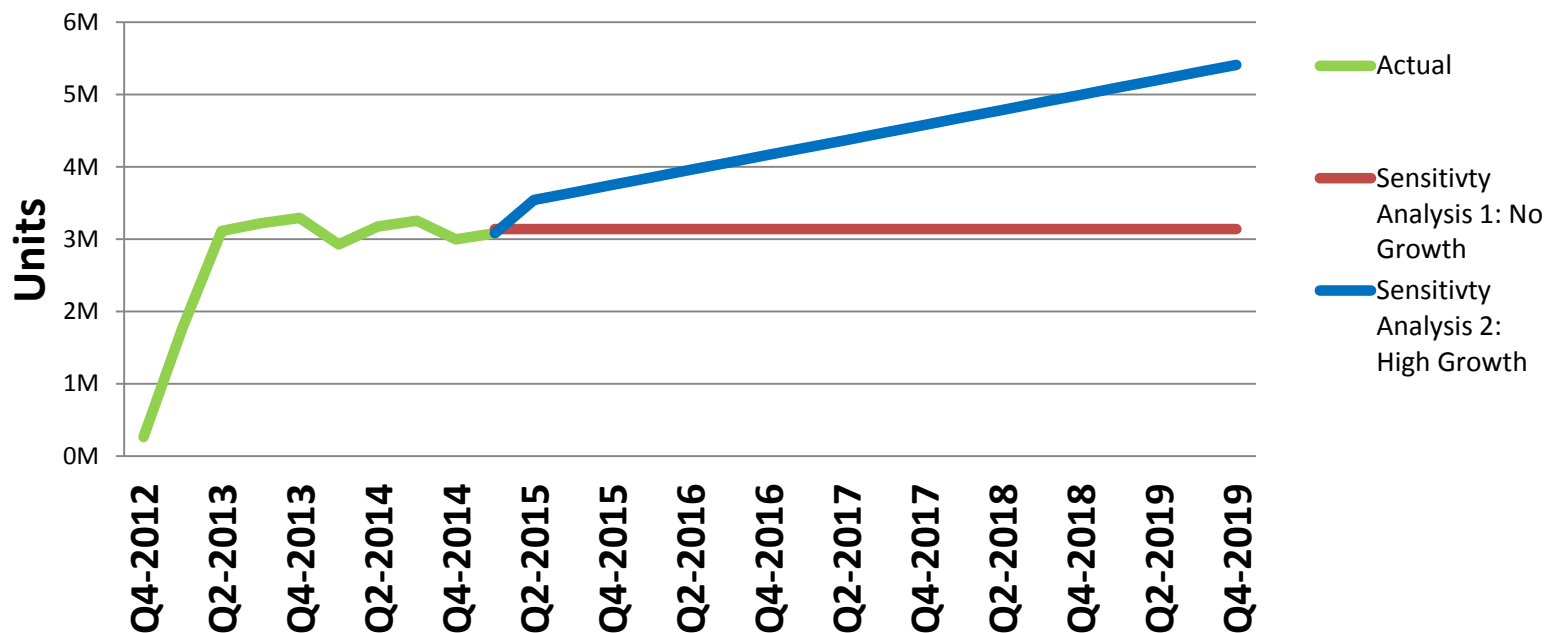
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- Given the limited historical trends for oxycodone CR (2 years: Q4-2012 to Q4-2014) and the difficulty in forecasting five years (2015–2019), two sensitivity analyses were conducted related to the expected future trends in oxycodone CR.
- The results provide an interval of where the potential market for oxycodone CR may be in 5 years. The two scenarios are viewed as the upper and the lower limits for the size of the oxycodone CR market in 2019:
  - ♦ **Sensitivity Analysis 1 – No growth**  
Oxycodone CR use remains at 2014 levels
  - ♦ **Sensitivity Analysis 2 – High growth**  
Oxycodone CR continues to grow at the rate of growth observed since its introduction into the market in Q4-2012

# Two sensitivity analyses

No growth vs. high growth in oxycodone CR

Volume of Units, Oxycodone CR, Canada Q4-2012 to Q4-2019



# Methodology

## Two assumptions

Oxycodone CR would be substituted for:

### Assumption 1 – OxyNEO and hydromorphone LA

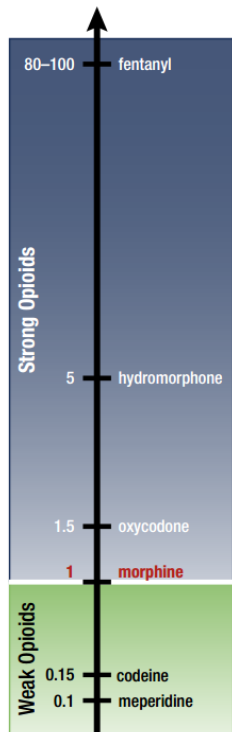
- The oxycodone CR use in public (mostly QC) (21%) and private (18%) plans will switch to OxyNEO
- Out-of-pocket use of oxycodone CR (61%) will switch to:
  - ♦ OxyNEO (11%)
  - ♦ Hydromorphone (50%) – next potent opioid with comparable price

Assignment based on observed distribution of opioids in the out-of-pocket market.

### Assumption 2 – OxyNEO, hydromorphone LA and fentanyl

- Public and private use (same as in Assumption 1)
- Out-of-pocket use of oxycodone CR (61%) will switch to:
  - ♦ OxyNEO (11%) and hydromorphone (50%)
  - ♦ Exception is oxycodone CR 80 mg, which will switch to OxyNEO (11%), hydromorphone (20%) and fentanyl (30%)

Assignment based on observed distribution of opioids in the out-of-pocket market.



# Oxycodone CR allocation to hydromorphone LA and fentanyl patch

- Oxycodone CR use allocated to OxyNEO ensured the matching of strengths

Oxycodone CR	Average unit price		Hydromorphone LA	Average unit price
5MG	\$0.33	→	3MG	\$0.70
10MG	\$0.46	→	4.5MG	\$0.84
15MG	\$0.54	→	6MG	\$1.05
20MG	\$0.68	→	9MG	\$1.39
40MG	\$1.15	→	12MG	\$1.82
60MG	\$1.53	→	18MG	\$2.63
80MG	\$2.08	→	24MG	\$3.38
			30MG	\$4.04

- Oxycodone CR use was allocated to hydromorphone LA as presented in the upper tables

- Oxycodone CR use was allocated to the fentanyl patch as presented in the lower tables

Oxycodone CR	Average unit price		Fentanyl patch	Average unit price
5MG	\$0.33	↗	12.5Y/1HR	\$2.40
10MG	\$0.46	↗	12Y/1HR	\$2.20
15MG	\$0.54		25Y/1HR	\$3.75
20MG	\$0.68		37.5Y/1HR	\$7.35
40MG	\$1.15		50Y/1HR	\$7.13
60MG	\$1.53		75Y/1HR	\$10.20
80MG	\$2.08		100Y/1HR	\$12.58

# Formulary listing – Oxycodone

Only Quebec lists oxycodone CR

	BC	AB	SK	MB	ON	QC	NB	NS	PEI	NL	NIHB
ACT OXYCODONE CR						EDS					
APO-OXYCODONE CR						EDS					
PMS-OXYCODONE CR						EDS					
OXYNEO	B	B	EDS	EDS	EAP	EDS	B	B			
OXYCODONE	B	B	B			B					LU
OXY-IR	B	B	B	EDS	B	B	SA	B	B	B	LU
PMS-OXYCODONE	B	B	B	EDS	B	B	SA	B	B	B	LU
SUPEUDOL	B	B	B	EDS	B	B	SA	B	B	B	LU

B= Benefit  
 EDS= Exception Drug Status  
 EAS= Exceptional Access Program  
 SA= Special Access  
 LU= Limited Use



# The distribution of units and sales by market segment, 2013

The 2019 markets for oxycodone products and other opioids were allocated to each of the three market segments (public, private and out-of-pocket) using the distribution observed in the 2013 Payer Insight databases.

Opioids	Public	Private	Out-of-pocket
Units	54%	25%	21%
Sales	56%	27%	17%

Oxycodone (all)	Public	Private	Out-of-pocket
Units	49%	29%	21%
Sales	47%	31%	22%

OxyNEO	Public	Private	Out-of-pocket
Units	48%	33%	19%
Sales	49%	32%	18%

Oxycodone CR	Public	Private	Out-of-pocket
Units	29%	18%	53%
Sales	21%	18%	61%

A large proportion of oxycodone CR use and sales are in the out-of-pocket market

# The price of OxyNEO

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- The average manufacture unit price for OxyNEO after market entry was in line with the corresponding price of OxyContin prior to market exit.
- From a PMPRB regulatory standpoint:
  - ♦ OxyNEO offered slight or no improvement over its comparator drugs.
  - ♦ OxyContin was the only therapeutic class comparator for OxyNEO.
  - ♦ The therapeutic class comparison conducted by the PMPRB established a ceiling price.
- The average manufacture unit price of OxyNEO after market entry was comparable to the PMPRB ceiling price.
- Over the period Q2-2014 to Q4-2014, the average manufacture unit price for OxyNEO increased slightly.

# Average manufacture unit price: OxyNEO vs. OxyContin

Strength	OxyContin	OxyNEO	
	Q2-2012	Q2-2012	Q4-2014
10 mg	\$0.8926	\$0.8984	\$0.9021
15 mg	\$1.0896	\$1.0848	\$1.0911
20 mg	\$1.3489	\$1.3481	\$1.3524
30 mg	\$1.8112	\$1.7831	\$1.7904
40 mg	\$2.3463	\$2.3341	\$2.3415
60 mg	\$3.3174	\$3.2329	\$3.2657
80 mg	\$4.3293	\$4.3205	\$4.3543
Data source: MIDAS™, IMS AG All Rights Reserved			

# 2019 prices – Assumptions in TRPDR

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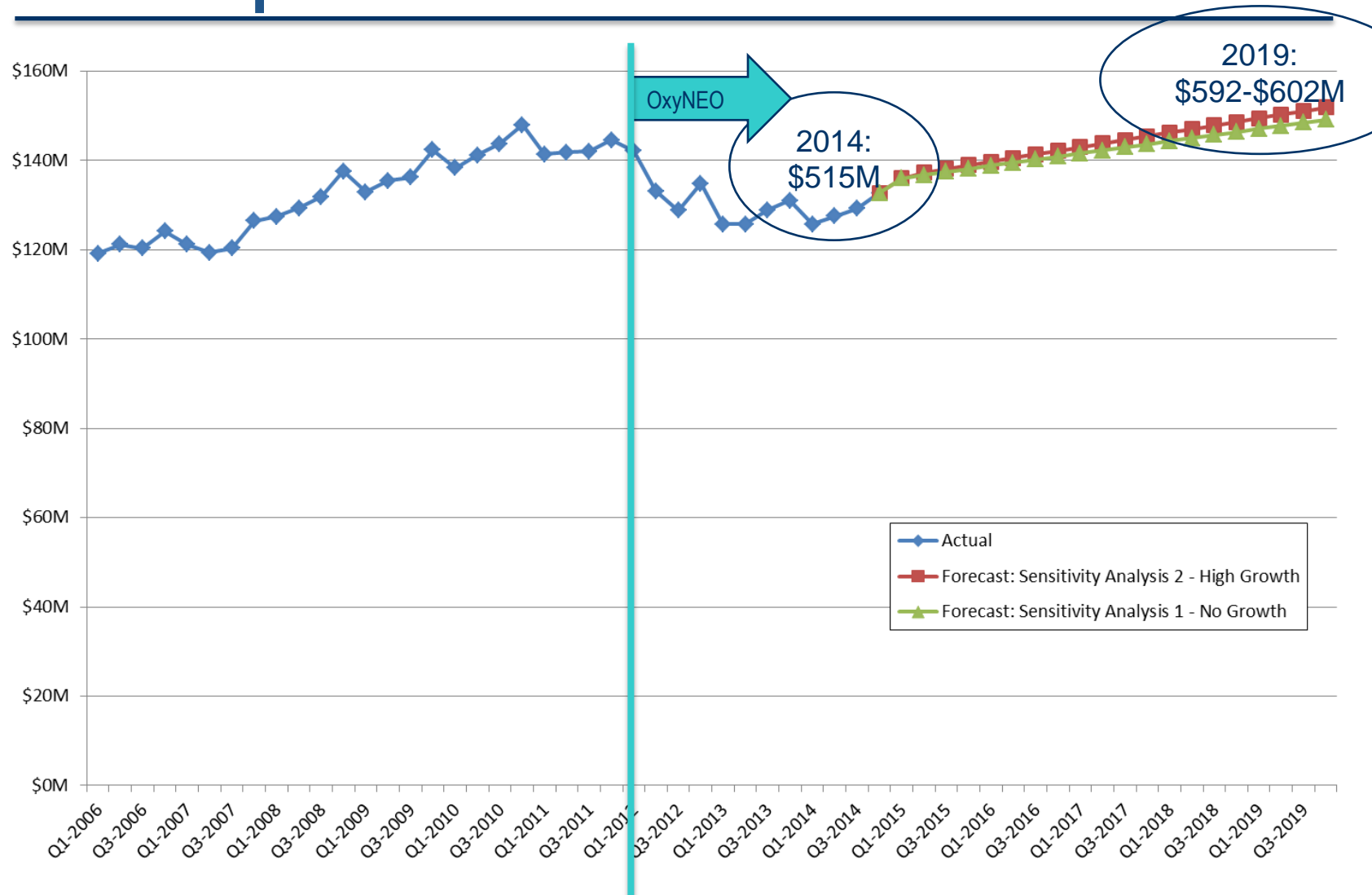
- **It is expected that in the coming years the price of OxyNEO will not markedly increase.**
  - ♦ The TRPDR cost impact analysis assumes an annual 1.3% CPI increase in determining the prices of OxyNEO in 2019.
  
- **For other opioids:**
  - ♦ For drugs that have had price increases in recent years, an annual 1.3% CPI increase was applied to estimate the 2019 prices.



## 4. Estimated cost impact of the TRPDR

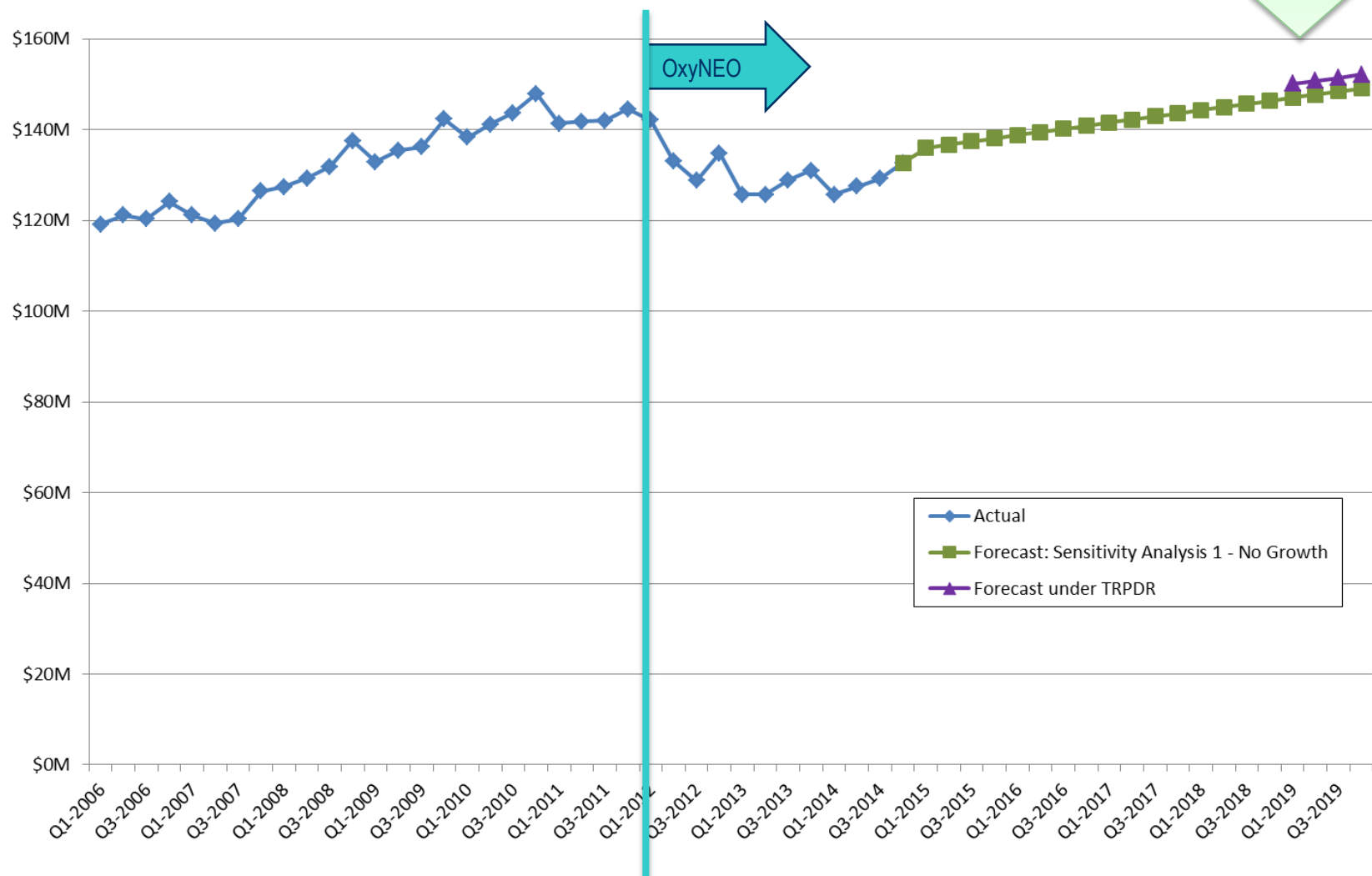
# Opioid market projections to 2019

## Status quo



# Opioid market projections to 2019

## Impact of TRPDR



# Estimated cost impact of the TRPDR

Assumption 1: Out-of-pocket market only switches to OxyNEO and hydromorphone LA

## ■ Sensitivity Analysis 1 – No growth in oxycodone CR

2019 Estimates	Status Quo			TRPD Regs	Estimated Impact	
	Opioids	Total Oxycodone	Oxycodone CR	Replaced Oxycodone CR	Amount	% difference
NATIONAL	\$592.4M	\$190.3M	\$14.8M	\$27.2M	\$12.4M	6.5%
Public (other)		\$79.9M	\$0.3M	\$0.6M	\$0.3M	0.4%
Public (QC)		\$9.7M	\$2.8M	\$5.7M	\$2.9M	30.4%
Private		\$59.2M	\$2.7M	\$5.6M	\$2.9M	4.9%
Out-of-pocket		\$41.4M	\$9.0M	\$15.2M	\$6.3M	15.1%

## ■ Sensitivity Analysis 2 – High growth in oxycodone CR

2019 Estimates	Status Quo			TRPD Regs	Estimated Impact	
	Opioids	Total Oxycodone	Oxycodone CR	Replaced Oxycodone CR	Amount	% difference
NATIONAL	\$602.3M	\$200.2M	\$24.7M	\$45.5M	\$20.8M	10.4%
Public (other)		\$80.2M	\$0.5M	\$1.1M	\$0.6M	0.7%
Public (QC)		\$11.5M	\$4.6M	\$9.5M	\$4.9M	42.7%
Private		\$61.0M	\$4.5M	\$9.4M	\$4.8M	7.9%
Out-of-pocket		\$47.5M	\$15.0M	\$25.5M	\$10.5M	22.0%



# Estimated cost impact of the TRPDR

Assumption 2: Out-of-pocket market switches to OxyNEO, hydromorphone LA and fentanyl patch (minimal variation in impact compared to Assumption 1)

## ■ Sensitivity Analysis 1 – No growth in oxycodone CR

2019 Estimates	Status Quo			TRPD Regs	Estimated Impact	
	Opioids	Total Oxycodone	Oxycodone CR	Replaced Oxycodone CR	Amount	% difference
NATIONAL	\$592.4M	\$190.3M	\$14.8M	\$25.87M	\$11.1M	5.8%
Public (other)		\$79.9M	\$0.3M	\$0.6M	\$0.3M	0.4%
Public (QC)		\$9.7M	\$2.8M	\$5.7M	\$2.9M	30.4%
Private		\$59.2M	\$2.7M	\$5.6M	\$2.9M	4.9%
Out-of-pocket		\$41.4M	\$9.0M	\$13.9M	\$5.0M	12.0%

## ■ Sensitivity Analysis 2 – High growth in oxycodone CR

2019 Estimates	Status Quo			TRPD Regs	Estimated Impact	
	Opioids	Total Oxycodone	Oxycodone CR	Replaced Oxycodone CR	Amount	% difference
NATIONAL	\$602.3M	\$200.2M	\$24.7M	\$43.28M	\$18.6M	9.3%
Public (other)		\$80.2M	\$0.5M	\$1.1M	\$0.6M	0.7%
Public (QC)		\$11.5M	\$4.6M	\$9.5M	\$4.9M	42.7%
Private		\$61.0M	\$4.5M	\$9.4M	\$4.8M	7.9%
Out-of-pocket		\$47.5M	\$15.0M	\$23.3M	\$8.3M	17.5%

# Limitations

This analysis makes important assumptions in its projections

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- **Forecasts five years of opioid utilization (2015–2019) based on nine years of data (2006–2014).**
  - ♦ In the case of OxyNEO, only three years of data (2012–2014) were available and were used to forecast to 2019.
  - ♦ In the case of oxycodone CR only two years of data (2013–2014) were available and were used to forecast to 2019 (further discussed in the next slide).
- **The breakdown of the national use and sales of opioids (including oxycodone CR) for 2019 was based the breakdown observed in 2013. This distribution may evolve over time and may be slightly different in 2019.**

# Limitations (cont'd)

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- The analysis does not take into account the market entry of additional oxycodone tamper-resistant products supplied by different manufacturers, and the impact that this may have on the price of the tamper-resistant version in 2019.
- The analysis does not project the cost implications beyond 2019.
  - ♦ OxyNEO is expected to lose patent protection in 2026, which would mean that the estimated cost implications are expected to extend over an eight-year period.

# Conclusions

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- It is estimated that the Canadian sales for opioids would be in the range of \$592.4 to \$602.3 million by 2019, with oxycodone sales ranging from \$190.3 to \$200.2 million.
- The sales for the controlled released version of oxycodone were estimated to be in the range of \$14.8 to \$24.7 million, depending on the future uptake of this relatively new drug.
  - ♦ The out-of-pocket market makes up the largest share of the sales, estimated to be in the range of \$9.0 to \$15.0 million.
  - ♦ The private payer and the Quebec public payer markets were estimated to be fairly comparable in terms of sales, each estimated to be in the range of \$2.7 to \$4.6 million.

# Conclusions (cont'd)

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- **The cost impact of the TRPDR for the Canadian national market was estimated for 2019 to range from \$11.1 to \$20.8 million, depending on the future uptake of this relatively new drug as well as assumptions of the switching to hydromorphone LA and the fentanyl patch.**
  - ♦ The out-of-pocket market would be the most impacted, with \$5.0 to \$10.5 million increased sales.
  - ♦ The impact on private payer and the Quebec public payer markets were estimated to be similarly. Each would see an increase in sales ranging from \$2.9 to \$4.9.



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# THANK YOU

Patented Medicine Prices Review Board