



Patented Medicines Costs of Private Insurers: PMPRB Implications

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ABSTRACT

On July 1, 2020 the Government of Canada will implement sweeping changes to the Guidelines used by the Patented Medicine Prices Review Board (PMPRB) to regulate the prices of patented medicines. The new rules are expected to reduce average maximum allowable prices by 52% to 84% from the current regulated price ceiling. The government and the insurance industry have argued that the PMPRB needs the additional regulatory powers because the prices of patented medicines are causing a sustainability crisis for private insurers in Canada. This study tested the validity of that assertion. Total claims costs of private insurers from patented medicines were estimated using data from the Canadian Institute for Health information (CIHI) and the PMPRB. Costs were counted at manufacturers list prices, which are the target of the regulations. Patented medicines costs were compared to other extended health benefits covered by private insurers. The results show that the costs attributable to dental benefits are larger than the costs attributable to patented medicines. Over the most recent 10 years, costs for dental, vision and other professionals have grown faster than patented medicines costs. The findings challenge the legitimacy of one of the fundamental justifications for the new price regulations.

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INTRODUCTION

The Patented Medicine Prices Review Board (PMPRB) is the quasi-judicial federal agency that regulates the prices of patented medicines in Canada. On July 1, 2020 the Government of Canada will implement changes to the regulatory Guidelines used by the PMPRB to set maximum allowable prices. The Government's explicit regulatory goal is to reduce the cost of patented medicines. The PMPRB estimated that the regulations will reduce price ceilings for patented medicines by approximately 52% from the current price level.¹ The impact is likely to be much larger. An independent study demonstrated that the changes in the Guidelines will impose price cuts up to 84%.²

One of the main justifications offered by the PMPRB for the new Guidelines was the impact of patented medicine prices on the sustainability of prescription drug costs for private insurers.³ Indeed, the private insurance industry advocated in favor of the new regulations citing the same rationale.^{4,5} However, the PMPRB and the private insurance industry have not shown that total spending on patented medicines is unaffordable or uninsurable. They have merely asserted that the prices of patented medicines are too high. Or that high cost drugs represent a growing share of total prescription drug expenditures.

If the cost burden of patented medicines is no greater than the cost burden of unregulated health benefits, then there is no sustainability crisis to justify new price regulations.

This study tested the validity of the assertion that the prices of patented medicines are causing a sustainability crisis for private insurers in Canada. It estimated the claims costs of private insurers that are directly attributable to patented medicines. The costs were compared to other health benefits covered by private insurers. Of all the health benefits covered by private insurers only patented medicines are subject to price regulation in Canada. This study assumed that if the cost burden of patented medicines is no greater than the cost burden of unregulated health benefits then there is no sustainability crisis to justify the new price regulations.

DATA AND METHOD

This analysis used data from the Canadian Institute for Health information (CIHI) and the Patented Medicine Prices Review Board (PMPRB) to estimate the claims costs of private insurers that are directly attributable to the prices of patented medicines.

¹ CG2 (2019). Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements): SOR/2019-298. Canada Gazette, Part II, Volume 153, Number 17. Registration: SOR/2019-298, August 8, 2019. PATENT ACT: P.C. 2019-1197 August 7, 2019.

² Rawson, Nigel SB; Lawrence, Donna (2020). New Patented Medicine Regulations in Canada: Updated Case Study of a Manufacturer's Decision-Making about a Regulatory Submission for a Rare Disorder Treatment. Canadian Health Policy, January 2020.

³ CG2 (2019).

⁴ CLHIA. (2016). CLHIA response to PMPRB Guidelines Modernization Discussion Paper. Canadian Life and Health Insurance Association Inc.

⁵ CLHIA. (2019). CLHIA welcomes amendments to the Patented Medicine Prices Review Board Regulations: News Release. August 9. Canadian Life and Health Insurance Association Inc.

The time frame for this study was determined by the availability of sales data for patented medicines in Canada. The PMPRB is the official government source of expenditure data specific to patented medicines. The most recent data available at the time of this analysis covered the years 1990 to 2017.⁶ The data are obtained by the PMPRB from patentees who are required by regulation to report their national total annual sales from patented and off-patent brand (and licensed branded-generic) drug products. The sales data are reported at the manufacturer's gross factory list price. The PMPRB reports sales data for patented medicines separately from off-patent brand drugs but does not report sales of patented medicines separately by payer source. Therefore, it was necessary to estimate the sales of patented medicines financed by private sector insurance using additional data from CIHI.

CIHI annually publishes data on the national health expenditures of private insurers. The most recent data available at the time of this analysis covered the years 1988 to 2017.⁷ The data are obtained by CIHI from the total health claims costs reported by the Canadian Life and Health Insurance Association, casualty insurance companies with corporate affiliations to life insurance companies and not-for-profit insurance companies. CIHI publishes the data by type of health expenditure. The types of expenditure for which data were available include: Hospitals, Physicians, Dental Services, Vision Care Services, Other Professionals (chiropractors, physiotherapists, etc.), Prescribed Drugs, Over-the-Counter Drugs, Personal Health Supplies, Administration, and other Health Care Goods and Services. CIHI does not publish separate data for patented versus non-patented (i.e. off-patent brand drugs and generics) prescribed drugs. The CIHI data definition for expenditures of private insurers on prescribed drugs aggregates patented and non-patented products and is reported at final retail prices that include manufacturer list price plus wholesale and retail markups, pharmacy fees and applicable taxes.

Costs were counted at manufacturers list prices because that is the target of the regulations. The analysis assumed that the private insurers portion of patented medicines sales was the same as that reported for total prescribed drug costs. The claims costs of private insurers that were attributable to patented medicines were estimated by first calculating the proportion of the total national public sector and private sector prescribed drugs costs reported by CIHI, that were paid by private insurers. The percentage attributable to private insurers was multiplied by the total sales of patent medicines reported by the PMPRB. All data and calculations are shown in Tables 1-2 in the appendix to this paper.

RESULTS

TABLE 1 shows the source data and calculations used to estimate private insurers claims costs for patented medicines separately from other types of prescribed drugs. For the year 2017, CIHI reported \$32.27 billion in total national public and private sector expenditures on patented and non-patented, outpatient prescribed drugs (excluding drugs used in hospital), measured at final retail prices. For the same year, PMPRB reported \$21.15 billion in total national public and private sector sales of patented and off-patent branded prescribed drugs, of which patented medicines accounted for \$16.80 billion. Subtracting sales of patented medicines from total sales of branded drugs leaves a remainder of \$4.35 billion accounted for by off-patent brands. PMPRB data also show \$5.80 billion in sales of generics in 2017. All sales reported by the PMPRB are measured at manufacturer gross list prices and include in-hospital and outpatient prescribed drugs.

⁶ PMPRB (2018). Annual Report 2017. Patented Medicine Prices Review Board.

⁷ CIHI (2019). National Health Expenditure Database, 1975 to 2019. Canadian Institute for Health Information.

CIHI also reported \$11.93 billion was spent nationally by private insurers on prescribed drugs in 2017. Expenditures of private insurers on prescribed drugs were calculated to be 37.0% of the \$32.27 billion in total national public sector and private sector expenditures on prescribed drugs reported by CIHI for the same year. The private insurers share of total prescribed drugs costs was applied to the sales reported by the PMPRB. The resulting estimate of private insurers prescribed drugs costs for 2017 are as follows: all branded drugs (\$7.82 billion), patented medicines (\$6.21 billion), off-patent brands (\$1.60 billion) and generics (\$2.14 billion).⁸ The remainder is accounted for by distribution costs (\$1.97 billion).

CHART 1. 2017 Private Insurers Claims Costs Compared: \$millions.

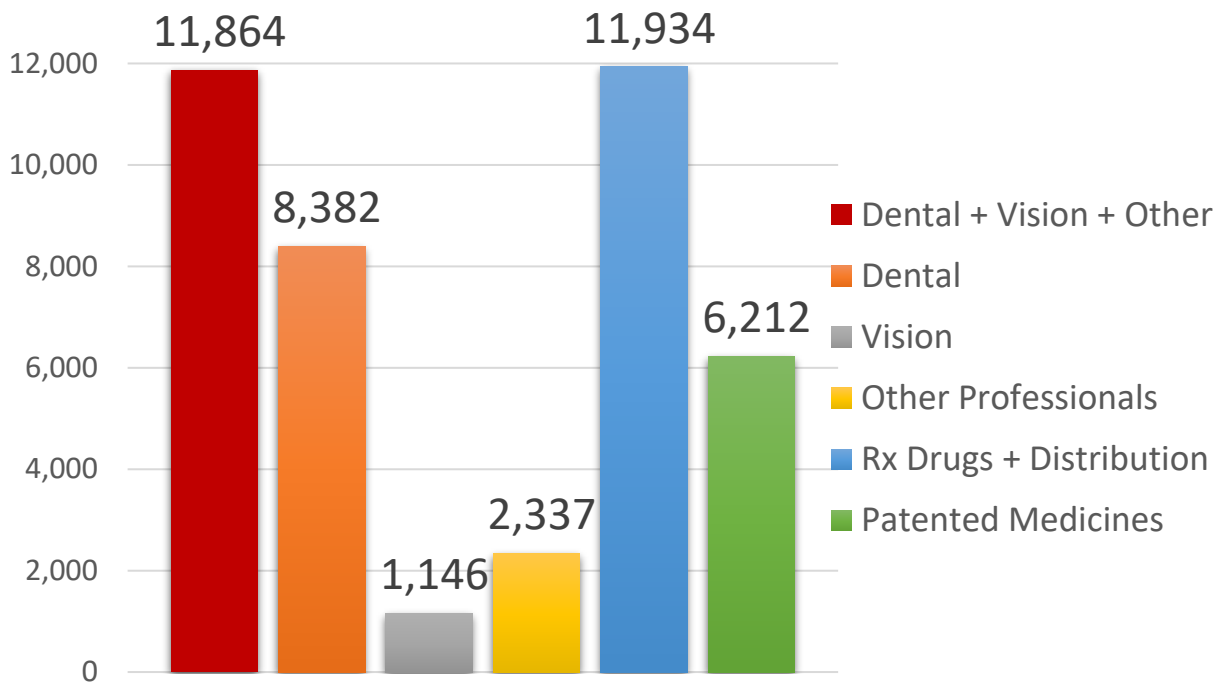


CHART 1 displays separate bars representing claims costs of private insurers attributable to each of dental, vision, other non-physician health professionals and patented medicines plus separate bars aggregating dental, vision and other professionals, and total prescription drugs related costs. The data show that insurers spend as much on the services of dentists, optometrists and other non-physician health professionals like chiropractors and physiotherapists (\$11.86 billion) as they spend on patented and non-patented prescription drugs and related distribution costs including pharmacists (\$11.93 billion). When the aggregated costs are shown separately the data indicate that private insurers claims costs for dental services (\$8.38 billion) far exceed the claims costs attributable to patented medicines (\$6.21 billion).

⁸ These estimates overstate the amounts attributable to each sub-category of prescribed drugs spending because hospital spending on drugs is excluded from CIHI data but is included in the PMPRB data. Separate data were available for hospital spending on drugs from CIHI's 2016 to 2019 editions of Prescribed Drug Spending in Canada: A Focus on Public Drug Programs. However, the data only covered the years 2014 to 2017. If the data had been included for the year 2017 the corresponding estimates for private insurers spending on prescribed drugs would be no greater than: all brands \$7.30 billion, patented medicines \$5.80 billion, off-patent brands \$1.50 billion and generics \$2.01 billion.

CHART 2. 2007 to 2017 Growth of Private Insurers Claims Costs Compared.

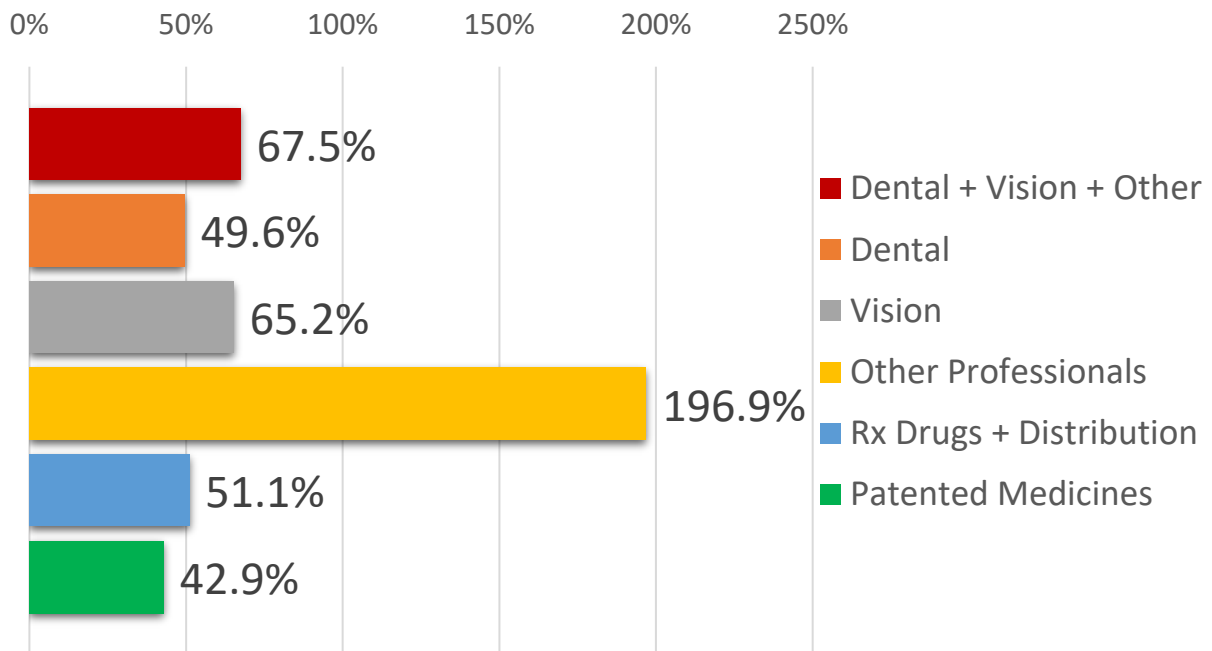
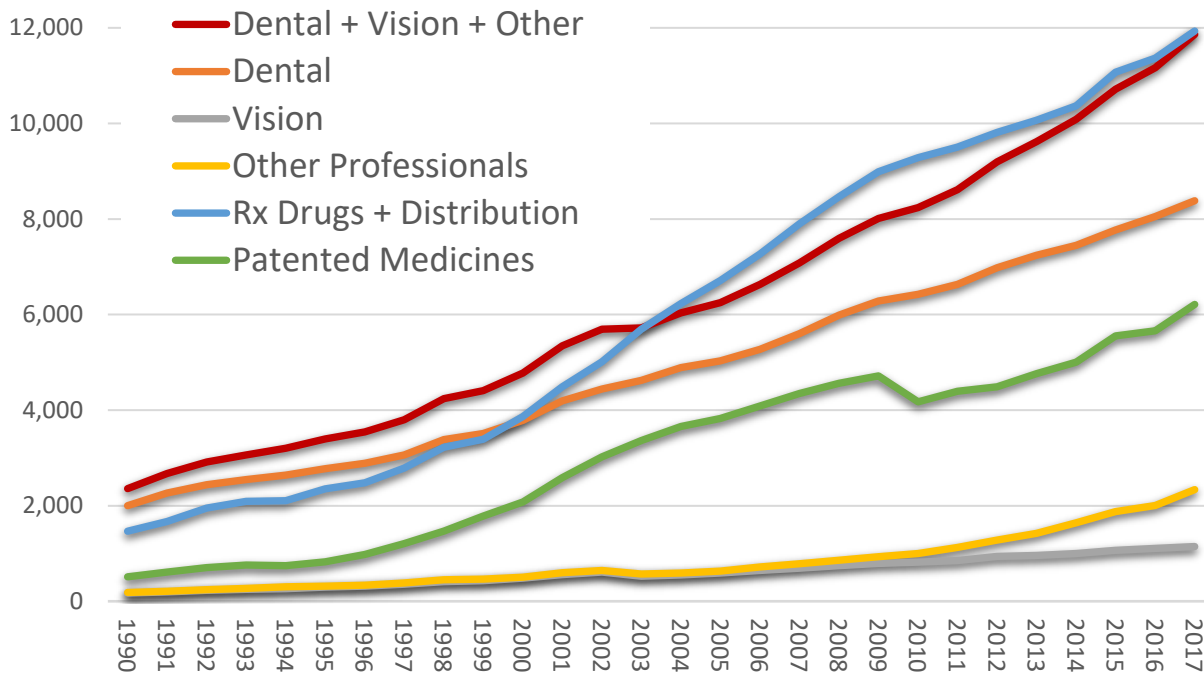


CHART 2 displays the growth of private insurers claims costs attributable to the same categories that were previously shown in CHART 1. Growth is calculated over the most recent 10 years from December 31, 2007 to December 31, 2017 and is stated as a percentage change over the entire period. The chart data show that aggregate claims costs for dental, vision and other professionals together (67.5%) grew faster than the aggregate claims costs for all prescribed drugs plus distribution (51.1%) over the last 10 years. When the aggregated costs are shown separately the data indicate that claims costs grew slower for patented medicines (42.9%) than for dental (49.6%), vision (65.2%) and other professionals (196.9%).

CHART 3 displays private insurers claims costs over the entire study period from 1990 to 2017. The chart data show that from 1990 to 2003 aggregate claims costs for dental, vision and other professionals exceeded the aggregate claims costs for all prescribed drugs plus distribution. From 2004 to 2016 the reverse was true. However, by 2017 aggregate claims costs for all prescribed drugs plus distribution costs converged to be roughly equal to the aggregate claims costs for dental, vision and other professionals. Notably, claims costs for patented medicines remained significantly lower than the claims costs for dental over the entire 28-year period of the study.

CHART 3. 1990 to 2017 Private Insurers Claims Costs Compared: \$millions.



POLICY IMPLICATIONS

This study showed that spending by private insurers on patented medicines is sustainable. Private insurers claims costs from patented medicines are far lower than the claims costs from dental services; and have also grown slower than the claims costs from dental, vision or other health professionals. To justify the regulations the government, the PMPRB and the insurance industry have expressed particular concerns about the impact of high-cost drugs. Yet, according to PMPRB data there were 144 patented medicines defined as high-cost drugs in 2017 accounting for \$6.31 billion in gross sales.⁹ This study estimated that the private insurers share of expenditures on high cost drugs amounted to \$2.33 billion in 2017, which is far less than the claims costs for dental and about the same as the claims costs for non-physician health professionals like chiropractors and physiotherapists. High-cost drugs can cause localized affordability challenges within some individual drug plans, but this occurs mainly as a result of insufficient risk pooling. Many employer-sponsored drug plans essentially self-insure their employee population, utilizing the insurer merely for administrative services only. Industry-wide risk pooling is a solution and the Canadian Life and Health Insurance Association (CLHIA) offers such a scheme. Government could make it mandatory for all employer-sponsored drug plans to participate. This approach would be more legitimate than using the PMPRB as a cost manager for private drug plans.

⁹ PMPRB (2018). Annual Report 2017. Patented Medicine Prices Review Board. Figure 10. Share of Sales for High-Cost Patented Medicines, 2006 to 2017.

DATA TABLES

TABLE 1. Private Insurers Claims Costs for Patented Medicines: \$millions.

Year	TOTAL					INSURERS						
	A Prescribed Drugs	B Brands	C Patented	D Off- Patent	E Generic	F Prescribed Drugs	G % TOTAL	H Brands	I Patented	J Off- Patent	K Generic	L Distribution
1990	4,872	3,299	1,700	1,599		1,466	30.1%	993	511	481		
1991	5,466	3,895	2,000	1,895		1,671	30.6%	1,190	611	579		
1992	6,097	4,164	2,200	1,964		1,947	31.9%	1,330	703	627		
1993	6,600	4,748	2,400	2,348		2,089	31.7%	1,503	760	743		
1994	6,760	4,957	2,400	2,557		2,105	31.1%	1,544	747	796		
1995	7,400	5,330	2,600	2,730		2,350	31.8%	1,693	826	867		
1996	7,605	5,857	3,000	2,857		2,477	32.6%	1,908	977	931		
1997	8,532	6,288	3,700	2,588		2,785	32.6%	2,053	1,208	845		
1998	9,451	6,975	4,300	2,675		3,221	34.1%	2,377	1,465	912		
1999	10,240	8,316	5,400	2,916		3,387	33.1%	2,750	1,786	964		
2000	11,725	9,310	6,300	3,010		3,867	33.0%	3,070	2,078	993		
2001	13,174	10,732	7,600	3,132		4,489	34.1%	3,657	2,590	1,067		
2002	14,760	12,081	8,900	3,181		5,009	33.9%	4,100	3,021	1,080		
2003	16,424	13,631	9,700	3,931		5,693	34.7%	4,725	3,362	1,363		
2004	17,866	14,168	10,500	3,668		6,229	34.9%	4,940	3,661	1,279		
2005	19,122	14,231	10,900	3,331		6,714	35.1%	4,997	3,827	1,170		
2006	20,811	14,902	11,700	3,202	3,000	7,269	34.9%	5,205	4,087	1,118	1,048	1,016
2007	21,976	15,991	12,100	3,891	3,500	7,897	35.9%	5,746	4,348	1,398	1,258	893
2008	23,375	16,317	12,600	3,717	4,200	8,467	36.2%	5,910	4,564	1,346	1,521	1,035
2009	24,784	17,052	13,000	4,052	4,900	8,988	36.3%	6,184	4,715	1,469	1,777	1,027
2010	27,585	17,000	12,400	4,600	5,400	9,282	33.7%	5,721	4,173	1,548	1,817	1,745
2011	27,898	17,799	12,900	4,899	5,200	9,503	34.1%	6,063	4,394	1,669	1,771	1,669
2012	28,225	18,021	12,900	5,121	5,400	9,815	34.8%	6,267	4,486	1,781	1,878	1,671
2013	28,335	18,268	13,400	4,868	5,300	10,068	35.5%	6,491	4,761	1,730	1,883	1,694
2014	28,579	18,455	13,800	4,655	5,400	10,366	36.3%	6,694	5,005	1,688	1,959	1,713
2015	30,096	19,693	15,100	4,593	5,500	11,074	36.8%	7,246	5,556	1,690	2,024	1,804
2016	31,317	20,856	15,600	5,256	5,700	11,364	36.3%	7,568	5,661	1,907	2,068	1,728
2017	32,271	21,147	16,800	4,347	5,800	11,934	37.0%	7,820	6,212	1,608	2,145	1,969

NOTES

- A National Health Expenditure Database, 1975 to 2019, Canadian Institute for Health Information. Table G.14.1 Expenditure on drugs by type and source of finance in millions of current dollars, Canada, 1985 to 2019.
- B PMPRB 2017 Annual Report. Appendix 3: Pharmaceutical Trends - Sales. Table 19. Sales of Patented Medicines, 1990–2017.
- C PMPRB 2017 Annual Report. Appendix 3: Pharmaceutical Trends - Sales. Table 14. Total R&D Expenditures and R&D-to-Sales Ratios of Reporting Companies, 1988 to 2017.
- D D=B-C
- E PMPRB 2019. Generics360: Generic Drugs in Canada, 2018. FIGURE 1.1 Index of Canadian and international retail sales for generic medicines, 2006 to 2018.
- F National Health Expenditure Database, 1975 to 2019, Canadian Institute for Health Information. Table H.3 Private-sector insurance health expenditure by source of finance and use of funds in millions of dollars, Canada, 1988 to 2017.
- G $G=F/A$
- H $H=B*G$
- I $I=C*G$
- J $J=D*G$
- K $K=E*G$
- L $L=F-I-J-K$
- * All expenditure data rounded to 0 decimal places.

TABLE 2. Private Insurers Claims Costs Compared: \$millions.

Year	A Total Dental, Vision, Other	B Dental	C Vision	D Other Professionals	E Total Prescribed Drugs	F Patented Medicines
1990	2,357	2,001	172	184	1,466	511
1991	2,673	2,264	198	212	1,671	611
1992	2,912	2,440	228	245	1,947	703
1993	3,061	2,543	246	271	2,089	760
1994	3,201	2,639	261	301	2,105	747
1995	3,396	2,777	299	320	2,350	826
1996	3,547	2,891	316	340	2,477	977
1997	3,801	3,064	353	383	2,785	1,208
1998	4,239	3,384	408	447	3,221	1,465
1999	4,405	3,509	429	467	3,387	1,786
2000	4,776	3,785	486	505	3,867	2,078
2001	5,347	4,191	559	597	4,489	2,590
2002	5,695	4,441	609	645	5,009	3,021
2003	5,718	4,625	524	569	5,693	3,362
2004	6,034	4,892	552	590	6,229	3,661
2005	6,251	5,030	589	632	6,714	3,827
2006	6,631	5,270	644	717	7,269	4,087
2007	7,083	5,603	693	787	7,897	4,348
2008	7,594	5,988	747	859	8,467	4,564
2009	8,010	6,283	793	934	8,988	4,715
2010	8,240	6,422	820	998	9,282	4,173
2011	8,615	6,633	854	1,128	9,503	4,394
2012	9,197	6,977	941	1,279	9,815	4,486
2013	9,619	7,238	959	1,422	10,068	4,761
2014	10,087	7,446	1,001	1,640	10,366	5,005
2015	10,717	7,772	1,066	1,879	11,074	5,556
2016	11,164	8,049	1,109	2,005	11,364	5,661
2017	11,864	8,382	1,146	2,337	11,934	6,212
Dec31, 2007 to Dec31, 2017	67.5%	49.6%	65.2%	196.9%	51.1%	42.9%

A to E National Health Expenditure Database, 1975 to 2019, Canadian Institute for Health Information. Table H.3 Private-sector insurance health expenditure by source of finance and use of funds in millions of dollars, Canada, 1988 to 2017.

F TABLE 1.

* All expenditure data rounded to 0 decimal places.