

Survey of drug prices for 14 drugs with US government rights in patents listed in the FDA Orange Book

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Introduction

1. I am a research fellow from the University of Notre Dame Public Service Initiative Program, with an assignment working with Knowledge Ecology International (KEI), a non-profit organization located in Washington, DC. One of KEI's primary focus concerns access to affordable medical technologies.

2. In November of 2011, I was asked to compare the US prices and prices in high income foreign countries for several pharmaceutical drugs that are registered for sale in the United States. In each case, the firm marketing the pharmaceutical drug had listed at least one patent in the US FDA Orange Book that included a disclosure of US government funding in the invention.

Drugs Selected for the Comparison

3. The products were selected from a July 2011 list of FDA orange book patents. These patents were subsequently searched for disclosures of U.S. government in interests in the patents. A total of 32 products were identified, by their active pharmaceutical products, that included both listings in the Orange Book, and disclosures of government interests.

4. Of these 32 products, 14 are sold by Drugstore.com. I could find at least one foreign price in high income countries for all 14 of these products. These were, listed by generic name, with the US brand name in parenthesis.

- cetorelix (Cetrotide)
- darunavir ethanolate (Prezista)
- emtricitabine (Emtriva)
- exenatide (Byetta)
- lacosamide (Vimpat)

- linagliptin (Tradjenta)
- lopinavir + ritonavir (Kaletra)
- lovastatin (Lovastatin)
- paricalcitol (Zemplar)
- pregabalin (Lyrica)
- ritonavir (Norvir)
- rosuvastatin calcium (Crestor)
- sitagliptin phosphate (Januvia)
- tobramycin (Tobrex)

5. These drugs are used to treat a wide range of illnesses, including but not limited to heart disease, HIV/AIDS, diabetes, cancer, epilepsy and eye disease.

Foreign Countries In The Comparison

6. As noted above, the comparisons were limited to countries that the World Bank classifies as high income. The foreign prices were obtained from seven national drug reimbursement formularies, and one Canadian province reimbursement formulary. Countries included were Australia, Canada, Denmark, Italy, the Netherlands, New Zealand, Norway, Spain, and the United Kingdom. I have reported all countries I checked and all prices that I found.

7. According to September 2011 estimates by the International Monetary Fund, the 2010 gross domestic product (GDP) per capita for the United States and the nine foreign countries are as follows: Norway (\$84,144), Denmark (\$55,986), Australia (\$55,672), the Netherlands (\$46,986), United States (\$46,860), Canada (\$46,303), the United Kingdom (\$36,164), Italy (\$34,059), New Zealand (\$32,163), and Spain (\$30,639).

Drug Prices

8. Drugstore.com provides both its own prices for drugs, and reports the average retail price for each drug.

9. The prices of drugs in foreign countries were obtained by accessing the government websites for the drug reimbursement schedule. I was not able to find prices in all foreign countries, due largely to the more limited inclusion of some products of foreign reimbursement schedules.

10. The price of each drug in the survey is compared with the same drug manufactured by the same pharmaceutical company in the same dosage sold in different markets. The unit price for each drug is calculated by the price of each package of drugs divided by the number of units (such as tablets or capsules) in each package. Drugs sold in larger quantity tend to have a lower per unit price. Mindful of this fact, I have calculated the unit price of each drug using the most common packaging size sold across the countries researched. In the event that the most common packaging size is unavailable in a certain country, I calculated the unit price using the closest packaging size available and clearly denoted the difference. The website of the Ontario (Canada) government provides per unit prices only, with no information on quantity or package size.

Results

11. For 1 of the 14 products, Katetra - the combination of lopinavir and ritonavir that was first registered with the FDA on September 15, 2000, the price in the United States was lower than the price in Denmark, Italy and Spain, and higher than the price in Australia, Canada, Netherlands, Norway, NZ and the UK.

12. For 13 of 14 products, prices from drugstore.com are higher than any on the nine foreign countries, and at times significantly so.

13. Ritonavir (Norvir) is a HIV/AIDS medication sold in the United States and listed in the government websites of all the countries in the survey. In the United States, Norvir is being sold for \$9.33USD per 100mg capsule, or \$9.18USD per tablet. In no other countries on the list is the 100mg tablet or capsule sold for more than \$2.79USD per unit. In Ontario Canada, the price is \$1.16USD. In New Zealand, the price is \$1.15USD.

14. Also having a disproportionately high retail drug price in the United States is sitagliptin phosphate (Januvia), a diabetes medication. The price of this medication is available in all but one country in the survey (New Zealand). In no foreign market is Januvia being sold for more than \$3.37USD per 100mg dose. In the United States however, the same dosage is being sold for \$7.20USD, more than twice the price any consumer has to pay in any of the seven countries where pricing data for this drug is available.

15. Tobrex is another drug that cost American consumers significantly more than consumers in other countries. Tobrex is sold for \$72.53USD per 5ml bottle on drugstore.com, while none of the other 5 countries with available data is selling the same medication for more than \$19.92USD per 5ml bottle, slightly more than a quarter of what consumers in the U.S. pay for the exact same drug. In fact, aside from Australia, none of the other 4 countries sell Tobrex for more than \$14.30USD per 5ml bottle, which means that U.S. consumers are paying 5 times as much as consumers in Denmark, the Netherlands, New Zealand, and Norway.

16. A summary of the data is provided in the following table.

Brand name (generic name)	Disease	Drugstore .com price	US: Average retail price	Number foreign prices	Max foreign price	Minimum foreign price	Median foreign price
Cetrotide (cetorelix)	cancer	\$145.99	\$145.99	6	\$82.51	\$36.24	\$72.07
Prezista (ethanolate)	HIV/AIDS	\$17.67	\$20.04	9	\$16.39	\$7.95	\$11.25
Emtriva (emtricitabine)	HIV/AIDS	\$14.73	\$17.48	7	\$12.21	\$8.15	\$8.98
Byetta (exenatide synthetic)	diabetes	\$329.02	\$364.29	3	\$182.25	\$109.38	\$120.73
Vimpat (lacosamide)	epilepsy, diabetes	\$6.93	\$6.93	7	\$3.49	\$2.06	\$2.67
Tradjenta (linagliptin)	diabetes	\$7.67	\$8.44	1	\$2.65	\$2.65	\$2.65
Kaletra (lopinavir + ritonavir)	HIV/AIDS	\$3.06	\$3.65	9	\$4.11	\$2.05	\$2.78
Lovastatin (lovastatin)	heart disease	\$0.67	\$2.42	2	\$0.49	\$0.30	\$0.40
Zemplar (paricalcitol)	kidney disease	\$9.30	\$10.61	6	\$7.92	\$3.98	\$6.74
Lyrica (pregabalin)	pain, epilepsy, diabetes	\$2.87	\$2.87	7	\$1.84	\$1.00	\$1.40
Norvir (ritonavir)	HIV/AIDS	\$9.18	\$10.70	9	\$2.79	\$1.15	\$1.53
Crestor (rosuvastatin calcium)	heart disease	\$4.76	\$5.44	7	\$2.93	\$1.24	\$1.62
Januvia (sitagliptin phosphate)	diabetes	\$7.20	\$8.44	8	\$3.37	\$1.91	\$2.75
Tobrex (tobramycin)	antibiotic	\$72.53	\$77.31	5	\$19.92	\$5.12	\$9.03

District of Columbia

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