- Skip to content
- <u>Skip to menu</u>

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Search search	Q
RSS	
<ul> <li><u>Home</u></li> <li><u>Citizen Journalists</u></li> <li>Election 2009</li> </ul>	

- Grassroots Hub
- PPC Manifesto
- Videos and Photos

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## **Regulatory changes necessary to lower prescription drug costs**

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**Part Two of the Capitalist Manifesto for Healthcare Reform: Lowering prescription drug costs.** Adapted from a piece originally published by **Jimmy Sengenberger** in the Regis University Highlander newspaper.

Ronald Reagan once said, "Individual freedom and ingenuity are at the very core of everything we've accomplished."

Indeed, everything that has made America great has come from empowering the people, including and especially when it comes to the market. Capitalism has been the engine of prosperity for this country going back to its founding. As such, I am now proposing that Congress and the President consider the "Capitalist Manifesto for Healthcare Reform," several specific, free-market fixes for the healthcare problem.

In the first article of this series, I examined the importance of breaking down two critical barriers to competition: the third-party based system that sets consumers apart from paying and decision-making and state laws prohibiting insurance purchases across state lines. Cost and affordability, not quality of care, are the key issues with our healthcare system. So let's look at another way in which we can directly empower the individual beyond increased choice and expand affordability—by adjusting policies surrounding the importation of cheaper

prescription drugs.

**High Costs:** Prescription drug costs often contribute greatly to higher healthcare costs. According to the Kaiser Family Foundation, the number of prescriptions purchased in the U.S. between 1994 and 2004 was a whopping 68 percent, with prices averaging increases of 8.3 percent yearly during that period. "Although still only a modest part of total health care spending in the U.S (11 percent)," they note, "with so many people relying on prescriptions, the cost implications loom large for the American public, health insurers, and government payers." The problems lie in Research and Development spending—specifically, patents and FDA regulations—and the fact that importing prescription drugs is illegal under current U.S. law.

**Patents:** Both patents and FDA regulations are significant contributors to \$800 million in costs to launch a single new pharmaceutical product—costs which result in higher prices for consumers. First, patents are designed to give a company temporary monopoly on the product so that they can recover their R&D spending. A patent lasts 20 years, yet as the CATO Institute's Roger Pilon points out, "the effective life for drug patents is about nine years." Logically, the shorter the time, the higher companies must charge per unit during that time to make up for the costs. This process must be changed to permit the same amount of patent time that other products have.

**FDA Regulations:** Then there are regulations. Today, according to PHRMA, the process of discovery to FDA approval takes an average of 12 to 15 years. As such, many people who would accept the risks involved suffer during this time. As economist Milton Friedman suggested, "[T]he one big development you could make would be to go back [to the situation where you have] the FDA certify safety...but not efficacy, and let the market itself work in determining efficacy."

Indeed, the FDA should test only for safety and allow doctors and consumers to judge efficacy, which would decrease costs substantially and thus allow for cheaper medications. By altering the regulatory process, more innovation and development will result in addition to lower prices.

**Prescription Drug Importation:** Finally, current law makes it illegal for prescription drugs to come to the U.S. from anyone other than the American producer. As of now, they must be approved by the Food and Drug Administration (FDA) for importation. Consequently, competition between prescription drug providers is stifled, as U.S. manufacturers lack the incentive to cut prices to beat out lower-priced contenders. But individuals, states and cities are already beginning to avoid these laws and import drugs from other countries. This should be made official: by permitting the importation of lower-cost prescription drugs from countries like Canada, consumers will have a larger list of affordable, cheaper medications to choose from.

Of course, we do have a right to know if what we're buying hasn't been FDA, so what's to say that the government can't mandate that imported prescription drugs say "NOT APPROVED BY FDA" in big, bold letters and be placed in sections stating "NOT APPROVED BY FDA" in the pharmacy? Leave it up to me and my doctor, not big brother Sam, to decide whether or not I want to buy a cheaper drug from Canada, approved by their version of the FDA, instead of the more expensive product from Georgia.

There are other concerns as well. The Heritage Foundation's Nina Owcharenko, for instance, makes a good point: prescription drugs in other, Westernized countries are fixed in accordance with price controls, which would distort the international market and advantage foreign manufacturers.

However, we must recognize that the vast majority of R&D costs are being paid for by the Americans, with other countries essentially getting a free pass. The U.S. is the only nation where market dynamics of supply and demand play out in pharmaceuticals—and with good reason. Price controls in other countries, as Owcharenko points out, reduce R&D spending (not costs) for new drugs by as much as \$5 to \$8 billion each year and trials for new medical compounds by as much as 50-60 percent.

But as long as the ban on importation is in effect, American drug manufacturers are going to recoup their R&D costs here instead of pushing supply and demand principles on other countries—meaning higher prices for us. Essentially, prices are set differently in the U.S. from other countries, meaning the U.S. shoulders the cost burden.

By eliminating the importation ban, other countries will have no choice but to react to supply and demand principles, as American manufacturers will find it necessary to cut prices at home and raise them abroad. Thus, other countries will have to share in R&D costs, which is long overdue.

As Roger Pilon notes, pharmaceuticals can use contractual agreements (to do such things as restrict drug resale), limits on supply, and export pressures, among other things, to help ensure that foreign countries are not undercutting the company. In effect, American manufacturers will be encouraged to do whatever they can to discourage importation in order to maintain their market share, which can be done by lowering prices here and raising prices elsewhere.

Should the U.S. government repair the patent process, refocus FDA regulations and permit the importation of prescription drugs, Americans of all stripes will surely benefit from a noticeable reduction of healthcare expenses.

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