



November 20, 2009

Hon. Harry Reid  
Senate Majority Leader  
528 Hart Senate Office Building  
Washington, D.C. 20510

***Re: Drug Prices and Generic Pathway Provisions of Health Care Reform Legislation***

Dear Senator Reid:

We write to urge you to amend the Patient Protection and Affordable Care Act to more directly and effectively improve the affordability of pharmaceuticals by closing the Medicare Part D “donut hole” and negotiating Part D drug prices, speeding up the generic pathway for biologics, and insuring an appropriate baseline for future drug rebates. As state legislators who have long promoted affordable medicines both in our states and as leaders of the National Legislative Association on Prescription Drug Prices (NLARx), we have a particular interest in the pharmaceutical provisions of health care reform legislation.

As currently drafted these provisions fall short in several critical respects, with the result that Americans will continue to be overcharged for their medications, generic versions of life-saving drugs will be delayed, and savings that could help pay for health care access will be foregone.

Our concerns take on renewed urgency given the morally reprehensible actions of the pharmaceutical industry in raising wholesale prices of brand-name drugs about 9 percent in the 12 months that ended Sept. 30, even as the Consumer Price Index declined during the same period. We would say we are shocked, except that this same industry engaged in identical behavior in the run-up to passage of the Medicare Part D prescription drug benefit. As reported in yesterday’s New York Times, the price increases over the past 12 months could add more than \$10 billion to the Nation’s drug bill, which is on track to exceed \$300 billion this year – with a commensurate increase in human suffering as drugs are simply priced out of reach for many.

We have never understood the reluctance to require price negotiation under Medicare Part D, and it is fiscally imprudent to follow this same path as we move to expand access to health insurance to virtually all Americans. We are also very concerned that the extended timeframe for the generic pathway for biologics will freeze in place for decades exorbitant pricing for the most expensive life-saving drugs, well beyond what is reasonable to insure a return on investment and a fertile environment for innovation.

***We request that the health reform legislation be amended to: (1) Require price negotiation under Medicare part D; (2) Immediately close the “donut hole”; (3) Insure that rebate requirements are calculated from a baseline that predates the 12-month run-up of wholesale***

***prices; (4) Reduce the 12 years of data exclusivity offered to new products, and (5) Eliminate the “evergreening” loophole that will allow brand-name companies to make minor modifications to existing biologics and obtain a brand new 12-year market monopoly.***

**Medicare Part D Pricing.** The current Medicare Part D program is wasteful, expensive, and confusing -- and it doesn't even accomplish the goal of providing a comprehensive prescription drug benefit under Medicare. The formularies change on a regular basis, enrollees hit the infamous “donut hole” and lose coverage, and there are bait-and-switch tactics causing seniors to sign up with plans that subsequently fail to cover their medications, payment denials are routine and the route to appeal those denials not well understood or fully utilized.

Medicare part D is rife with problems. Passage of health care reform provides the opportunity to fix this program, while recouping wasted taxpayer and consumer dollars spent on overpriced drugs. Failure to do so will continue a fiscally unsustainable program and continue to deny affordable prescription drug coverage to our seniors. While the provisions that standardize the appeal process and limit somewhat the impact of the donut hole are a step in the right direction, they fall far short of what is needed.

**The Infamous “Donut Hole”:** A recent study found that about 25% of Medicare beneficiaries reached the coverage gap and about 4% reached the \$5,100 threshold, making them eligible for catastrophic coverage. According to the study, those reaching the donut hole were typically people with chronic illnesses who filled an average of five prescriptions each month. Along with cutting back on medications, these beneficiaries also stopped using an average of one in five prescriptions during the coverage gap. According to the study, Medicare drug benefit beneficiaries decrease their use of medications by 14% upon reaching the coverage gap.

**Overcharging by Design:** A July 2008 report by the House Committee on Oversight and Government Reform found that the prices paid for the drugs used by the dual eligible beneficiaries under Medicare Part D are significantly higher than the prices paid by Medicaid for the same drugs. The higher prices for the top 100 drugs produced a windfall of \$1.7 billion for drug manufacturers in 2006, the first year of Medicare Part D. The higher prices produced an even larger windfall of \$2 billion for the drug manufacturers in 2007. An earlier staff report in October 2007 found that Medicare Part D pays on average 30% more for drugs than does Medicaid and that this discrepancy in pricing produced a windfall worth over \$3.7 billion for drug manufacturers in the first two years of the Medicare Part D program.

Who benefits? A study by the Center for Economic and Policy Research (CEPR) analyzes the extent to which various groups of seniors benefited from this legislation. The report, "The Impact of the Medicare Drug Benefit on Health Care Spending by Older Households," found that ***most seniors experienced no reductions in their health care spending as a result of the Medicare Drug benefit.*** In fact, the study found there is only limited evidence that the Medicare drug benefit provided relief for older households, and for many seniors, the burden of health care costs actually increased. ***We strongly support having the federal government negotiate Medicare drug prices as is already done through Medicaid and the Veteran’s Administration, and closing the donut hole now, through industry price roll-backs.***

**Generic pathway for biologics.** We have serious concerns about the section in the Act that establishes an FDA approval process for generic versions of expensive biologic drugs. Biologics, which include important treatments for cancer, arthritis and diabetes, cost 22 times more on average than conventional drugs and are predicted to make up half of all new drug approvals within a few years.

Already government programs are straining to cover their cost. By 2006, 43% of the Medicare Part B budget was spent on the top six biologic drugs. Yet the provisions in the bill would give brand-name biologics 12 years of data exclusivity, *more than double the five years conventional drugs receive*, even though the pharmaceutical industry's own numbers show development costs are equivalent.

Sticking with the 12-year exclusivity provision is fiscally foolish and jeopardizes the long term sustainability of health care reform. Let's look at the numbers:

- The Congressional Budget Office estimated significant savings from S. 1695 - Biologics Price Competition and Innovation Act of 2007, which would have established an abbreviated regulatory procedure for licensing biological drugs that met certain requirements. The CBO said enacting S.1695 would reduce total expenditures on biologics in the United States by about \$25 billion between 2009 and 2018 (over that 10-year period, such savings would equal roughly 0.5 percent of national spending on prescription drugs, valued at wholesale prices). Direct spending by the federal government would decrease by \$46 million from 2009 to 2013, and by \$5.9 billion from 2009-2018.
- Another report, by economist Robert J. Shapiro, former undersecretary of commerce in the Clinton administration, found that "generic versions of the top 12 categories of biologic treatments with patent protections that have expired or that are due to expire in the near future could save Americans \$67 billion to \$108 billion over 10 years and \$236 billion to \$378 billion over 20 years."

**Evergreening.** We are even more concerned that the provisions include a loophole that will allow pharmaceutical companies to make minor modifications to the drugs and receive a brand new 12-year marketing monopoly. Rather than promote innovation, research and development, which is the purported rationale, these provisions will actually remove incentives for meaningful future innovation and block price-lowering generic competition indefinitely in many cases.

*We urge amendment of the bill's provisions for an the FDA approval pathway for generic biologic drugs to reduce the 12 years of data exclusivity offered to new products to a maximum of five (5) years. We also strongly support eliminating the evergreening loophole that will allow brand-name companies to make minor modifications to existing biologics and obtain a brand new 12-year market monopoly.*

We greatly appreciate your hard work and careful, steady leadership in moving health care reform forward. We are all strong supporters of that reform, and we are here to offer our assistance in seeing this legislation to the finish line. The pharmaceutical provisions are critical to the effectiveness and the fiscal sustainability of the health reform package.

If adopted, our recommendations will both increase access to health care by improving affordability for consumers, and reduce the government's costs, helping assure that the programs remain financially viable for years to come. It's a win-win approach we sincerely hope Congress will adopt.

Respectfully,



**Maine Representative Sharon Anglin Treat**

NLARx Executive Director; House Chair, ME Insurance & Financial Services Committee

**David Catania, District of Columbia Council Member at Large**

Chair, NLARx Board of Directors; Chair, DC Council Health Committee

**New Hampshire Representative Cindy Rosenwald**

Vice Chair for Policy, NLARx Board of Directors; Chair, NH House Health Committee

**Arizona Senator Meg Burton Cahill**

Member, NLARx Board of Directors

**West Virginia Senator Daniel Foster MD**

Secretary, NLARx Board of Directors

**Iowa Senator Jack Hatch**

Member, NLARx Board of Directors; Assistant Majority Leader; Chair, IA Health & Human Services Budget Subcommittee

**Maine Representative Anne Perry, NP**

Treasurer, NLARx Board of Directors; House Chair, ME Health & Human Services Committee

**Connecticut Representative Kevin Ryan**

Member, NLARx Board of Directors; House Chair, CT Labor and Public Employees Committee

**Vermont Senate President Pro Tem Peter Shumlin**

Member, NLARx Board of Directors