NATIONAL RETIREE LEGISLATIVE NETWORK (NRLN)

PRESCRIPTION DRUG COSTS AND NATIONAL HEALTH CARE A CALL FOR ACTION - AUGUST 2009

EXECUTIVE SUMMARY

The NRLN believes that taking immediate steps to implement the initiatives below will create immediate and measurable ways to generate savings needed to reach a positive solution to unjustifiably high prescription drug costs. These initiatives will simultaneously create hundreds of billions of dollars in savings that can be spent to offset national health care reform costs. These savings will end up in the hands of American consumers and will stimulate the US economy and long-term economic growth for our country.

The NRLN has advocated free market competition while also advocating safety in the production and marketing of prescription drugs. Congress should enable the safe and controlled importation and competitive bidding of prescription drugs and robust formularies. Furthermore, Congress should ensure that the FDA accelerates access to generic prescription drugs. Backlogs of generic drugs awaiting approval have exceeded five (5) years and must be eliminated by providing for user fees and the staff needed to expedite approvals. Equally important, agreements that restrain competition between brand and generic manufacturers such as pay-offs that keep lower-priced generic drugs off the market, must be outlawed.

The NRLN projects that if Congress acts to implement these initiates, 18% of the nation's $3,567 billion in projected prescription drug expenditures over the next ten (10) years can be saved. This 18% savings would amount to $630 billion:

Recommended Initiatives	$ Savings	% Savings
Importation, Re-importation	**$178 billion**	**5%**
Competitive Bidding	**$ 178 "**	**5%**
Generic Drug Market Share Growth of 16%	**$ 203 "**	**6%**
Elimination of Restraint if Trade Practices	**$ 71 "**	**2%**
TOTALS	**$ 630 "**	**18%**

If the pledge of $80 billion in savings by the pharmaceutical industry in June of 2009 will close 50% of the Medicare D doughnut-hole, then Congress could allocate $160 billion of this $630 billion savings for the virtual elimination of the doughnut hole. This would leave more than $400 billion that could offset the $1 trillion or higher cost of national health care reform over the next ten (10) years In other words, this $630 billion savings could potentially close 100% if the Medicare D doughnut hole and pay the equivalent of 40% or more of the bill for national health care reform.

SECTION 1: THE PRESCRIPTION DRUG MARKET AND RETIREE DEMOGRAPHICS

Americans over age 65 have been the largest consumers of prescription drugs. According to the Agency for Health Care Research and Quality, the average number of retail prescriptions per capita increased from 8.9 in 1997 to 12.6 in 2007. The percent of the U.S. population with a prescription drug expense in 2005 was 59% for those under age 65 and 91% for those 65 and older. These percentages changed little from 1997 when they were 59% and 86% respectively.

A February 14, 2008 article in USA Today reported that approximately 79,000,000 baby boomers (born 1946-1964) will start turning 65 in 2011. According to the U.S. Census Bureau, the number of Americans age 45 or older will grow to115 million by 2010. The Bureau also reports that in 2007, 50% of registered voters in the U.S. were age 45 or older. Those between ages 45-84 comprised 33% of registered voters, while those ages 65-84 represented 17%. According to U.S. Census projections, the number of **Medicare-eligible seniors will double to 70 million by 2030** and reach almost 82 million by 2050. Given this demographic trend, unless there is a massive shift in voter registration demographics, **the nation's largest voting bloc will be seniors in 2012.**

SECTION 2: PRESCRIPTION DRUG PRICE INFLATION AND PHARMA'S $80 B PROMISE IN PERSPECTIVE

Prescription drugs represent a steadily-rising share of U.S. health care cost inflation. The Kaiser Family Foundation's *Employer Health Benefits 2007 Annual Survey* details how surveyed firms rated the leading factors related to increases in health insurance premium inflation for 2007. The table below summarizes the contributing factors, in rank order, for large firms (200 or more workers) and all firms. The % shown reflects the combination of the two rating responses, "A Lot" or "Somewhat" affects increases.

The Kaiser Family Foundation Employer Health Benefits 2007 Annual Survey

PREMIUM INCREASE FACTORS	Rank	RATINGS FROM FIRMS WITH 200 OR MORE WORKERS	Rank	RATINGS FROM ALL FIRMS
Higher spending for prescription drugs	**1**	**95%**	**1**	**94%**
Higher spending for hospital care	2	94%	2	92%
Higher spending for medical technology	3	89%	6	85%
Higher spending for physician services	4	87%	4	88%
An aging population	5	85%	3	90%
Insurance Company Profits	6	75%	5	86
Workers using more services because they pay a small share of the total Cost of Services	7	68%	7	71%

The Kaiser Family Foundation "Medicare spending and Financing" Fact Sheet (May 2009) reported that prescription drug spending in the U.S. had risen to $228 billion, or 12% of the total of $1,878 billion spent on Personal Health Care in 2007. A September 2008 Kaiser Family Foundation report titled "Prescription Drug Trends" reported "**Retail prescription prices increased an average of 6.9% a year from 1997 to 2007."** It was also reported that consumer spending for prescription drugs is rising at a higher rate, with 2006 reported to have risen at 9% over 2005.

The NRLN calculated the ten-year projected expenditures on prescription drugs, 2008 – 2017, starting with 2007 base year expenditures of $228 billion and an assumed spending growth rate of 8% on average, which is conservative given the growth expected in the number of U.S. seniors over the next ten years. **Total drug expenditures over these ten (10) years, using this methodology are estimated to be $3,567 billion**.

The Pharmaceutical Research and Manufacturers of America (PhRMA) promise to save $80 billion over ten (10) years would therefore yield savings equivalent to 2.24% of total prescription drug spending, assuming this 8% compounding rate. This represents savings of less than 3% of total drug spending – and less than 1% of total U.S. health spending! While PhRMA's gesture is significant, its promised $80 billion in savings, even if it materializes, is trivial in comparison to the savings that could be generated by the market-based reforms expected from the initiatives supported by the NRLN and many other members of Congress.

A 2008 Health and Human Services Department report, titled "Health Spending Projections through 2017," validates the NRLN assumptions concerning health cost trends. HHS projected an 8.2% annual rate of increase in drug spending through 2017, with total costs rising to $515.7 billion in 2017, a 138% increase. **Using this data, the $80 billion PhRMA promise is amounts to a relatively trivial 2.09% of total prescription drug spending.**

SECTION 3: MANUFACTURING AND IMPORTING INGREDIENTS AND PRESCRIPTION DRUGS.

The prescription drug importation debate is in reality two debates: The first involves U.S. importation of drugs that American companies manufacture in the U.S. and sell at significantly discounted prices in other countries. The act of reselling these drugs through U.S. channels is called re-importation.

The second debate concerns the *direct importation* of drugs manufactured in other countries and imported to the U.S. Most American companies manufacture offshore and thus are de facto importers. Not surprisingly, American drug manufacturers oppose re-importation and importation of competitor's prescription drugs.

The fact is that most pharmaceutical ingredients used by American pharmaceutical companies are manufactured overseas. A January 20, 2009 *New York Times* article by Gardner Harris

reveals that “the critical ingredients for most antibiotics are now made almost exclusively in China and India.” The same is true for other crucial medicines used for such things as diabetes and high blood pressure.

The NYT article reports that **of the 1,154 pharmaceutical plants mentioned in generic drug applications to the FDA in 2007, only 13% were in the United States,** 43% were in China, and 39% were in India. Overall, one federal database lists 3,000 overseas drug plants while another lists 6,800 plants.

“Drug labels often claim that the pills are manufactured in the United States, but the listed plants are often the sites where foreign-made drug powders are pounded into pills and packaged,” according to the *New York Times*.

American drug manufacturers are a part of the offshore problem. Ingredients and pills processed offshore are sold into foreign countries at much lower prices than in the U.S. which places the American consumer in the position of having to pay excessive prices that effectively subsidize foreign cost of sales and expenses.

The American public, particularly retirees and all seniors, pay artificially inflated high prices for pharmaceutical products and demand a stabilized marketplace where open competition from designated countries naturally lowers the price of medicine.

The NRLN estimates that **a well managed importation plan for prescription drug ingredients and finished products will save U.S. consumers 5% of $3,567 or $178 billion over the next ten (10) year period).** Readily achievable quality standards and controls and an adequately staffed and funded FDA can make stabilization and lower drug prices a reality for Americans retirees and all seniors.

SECTION 4: COMPETITIVE BIDDING OF PRESCRIPTION DRUGS

The Centers for Medicare and Medicaid Services (CMS) should be allowed to construct a robust Medicare-D formulary and issue Request for Quotes (RFQ’s) for prescription drugs paid for via the Medicare Prescription Drug Program. This practice has served the Veterans Administration well, although some say the VA formulary is not broad enough to serve everyone’s needs. Medicare Advantage Plans offer some formulary solutions, but these plans may lose large government subsidies. Insurers say such loses would cause significant premium increases.

In 2007, Medicare spent $44 billion on drugs, or 19.2% of the $228 billion spent in the U.S. on prescription drugs, according to the Kaiser Family Foundation (“Medicare Spending and Financing,” May 2009). The KFF report projected that 2009 prescription drug payments to all Medicare Drug Plans will be $53.2 billion, which is 11% of total Medicare payments under Plans A, B, and D.

The NRLN estimates that competitive bidding would reduce prescription drug costs over the ten (10) year period by a minimum of 5% of $3,567 billion or $178 billion

SECTION 5: THE CASE FOR BREAKING THE GENERIC DRUG LOG JAM

In AARP's May of 2006 Bulletin, Barbara Basler reported that generic drugs accounted for 56% of all prescriptions filled and that there was an FDA backlog of 800 generic drugs to be approved. She reported that the time the FDA took to approve new brand drugs was less than nine (9) months but that it was taking seventeen (17) months to approve a generic drug.

An April 2006 FDA study revealed that there were just 200 members of the FDA staff assigned to test and approve 975 submitted generic drug applications annually or one staff member for every 4.88 applications. At a rate of 4.88 per staff member and given the seventeen (17) month approval interval it would have taken 5.5 years just to clear the generic backlog.

By comparison, Brand Name drug applications receive VIP treatment. The study reported that the FDA assigns 700 staff members to test and approve 150 brand drug applications annually, or one staff member for every 0.21 applications, on average. The study reveals that brand manufacturers pay user fees to make sure the FDA is adequately staffed to approve brand drugs. The FDA does not even offer generic drug makers the option, let alone require them, to pay user fees to fund expedited generic drug approvals.

The study noted that:
When two generic drugs compete with a brand drug that market prices drop 50%.
When three generic drugs compete with a brand the market prices drops 75%.
The FDA study didn't state savings for one-on-one competition – use 25%.

Gary Bueller, the Director of FDA's Generic Drugs division, told *Forbes* (August 29, 2008) that the interval to review a generic drug had lengthened from 17 to 19 months and that generic applications for 2008 were expected to be 1,500 or a **54% increase over 2006.**

In 2007, sales of prescription drugs were $228 billion. If 56% of the prescriptions filled were generic then the generic sales would have been roughly $128 billion. Setting a generic drug expenditure goal of 75% of total prescription drug sales (**a 19% increase in market share) could save over $203 billion over ten (10) years.** This calculation is based on a conservative 30% savings estimate for every brand drug displaced and assumes expenditures of $3,567 billion over ten (10) years: **(.19 x $3,567 billion x .30 = $678 billion x .30 = $203 billion).**

SECTION 5: BRAND AND GENERIC DRUG MAKER COLLUSION

The Washington Post, in a February 3, 2009 article, written by Lyndsey Layton, reported that the Federal Trade Commission ("FTC") has found that nearly half of the patent settlements between generic drug makers and brand-name manufacturers in fiscal 2006 and 2007 resulted in some kind of payment to the generic maker in exchange for a pledge to stay out of the marketplace.

These payments – called **"pay-for-delay", "reverse payments" or "exclusion payment settlements"** – keep generic drugs off the market that could be 80 or 90% less costly for consumers. FTC officials say these deals violate anti-trusts laws, and deny consumers of less-expensive drugs, and allow brand drug makers a monopoly. "We want to stop these

unconscionable pay-for-delay deals that force consumers to overpay for much-needed drugs" said Jon Leibowirz, an FTC commissioner and the FTC's newly-appointed chairman.

Courts have been slow to declare such deals illegal. In two cases so far where the FTC has tried to persuade the Supreme Court to hear the cases, the Department of Justice intervened and argued that the Supreme Court should not take the case. The NRLN wants Congress to **immediately pass legislation that is clear and enforceable. Congress should ask the President to tell the Justice Department to enforce our antitrust laws**.

The NRLN speculates that **stopping these practices could save 2% or $71 billion of the prescription drug spending projected over the next ten (10) year period**.

The Hatch-Waxman Act of 1984 intended to speed generic drugs to market, but did not adequately address this practice. Sen. Herb Kohl (D-Wis.) and others, including then-Sen. Barack Obama, introduced legislation last year that would prohibit reverse payments. Congress should pass it, now.

SUMMARY

Retirees have the most to lose if Congress does not take steps to enact legislation that could free up total potential savings of $630 billion or 18% of total projected prescription drug expenditures, over the next ten (10) years. If $80 billion in savings (pledged by PhRMA) closes 50% of the Medicare D doughnut hole, then Congress could allocate another $80 billion of these saving to completely and more quickly eliminate the 'doughnut hole' in Part D coverage. This would leave another $470 billion to help offset the costs of national health care reform legislation over the next ten (10) years. In other words, the savings from the four prescription drug reforms in this paper could close 100% of the Medicare D doughnut hole and offset the equivalent of 40% or more of the overall cost of national health care legislation.

The retiree associations of the NRLN urge Congress to face the fact that drug prices in this country are artificially inflated due to market failure – and that this disproportionately impacts retirees living on fixed incomes. Global competition and industry restructuring is tough, but it is the path we chose as a country. The auto, airline, steel, chemical, telecommunications and other high-tech industries have become lean, aggressive and are compelled to compete for markets on a global basis. Drug companies have no excuse not to do the same.

APPENDIX – Prescription Drug Cost Impact on Health and Disposable Income

A sampling of reports from individual retirees and media reports:

Occasionally, I receive a prescription from a doctor at the VA because the RX he prescribes is not available through the VA line. Example: one month ago, I received an Rx for allergy/decongestant. That specific Rx was (is) not available through the VA channels since it is not a "generic". At Walgreen, a three-month supply would have cost me $220.00. At Walmart, the price was $200.00. Too expensive for me! Then, I went "on-line" and connected with a pharmacy in Canada. A SIX-MONTH SUPPLY would cost me $110.00. Yet, we are not officially allowed to receive drugs from Canada!

Claude Isnard
Pearland, TX
Lucent Technologies Retiree

I have recently experienced a situation, when I ordered a refill of one medication, the pharmacist told me that the cost for a 30 day supply was $800.00 plus! They stated that they had talked to the Insurance Company and the Brand name drug company. They said they could not do anything about it. Wow!

We contacted our doctor and he researched various alternates and options and found a medication that cost me $10.00. This is an example of the awful disregard for the public individual.

Jim Marot
Parker, CO

Delphi Corporation

"I am a diabetic for a number of years with no other means of getting my medication or having the routine 3 month check up. I won't be able to receive diabetic supplies any longer. For me it really does mean getting health insurance or eating." Declaration of xxxxx xxxxx

"I have stopped taking two of my medications, and am taking the most critical one every other day. And all of this before Delphi's latest move. This has literally placed [my wife] and I before the firing squad. The execution will take place on April 1st this year." *Id*. Ex. I (March 18, 2009 email from Mr. xxxx).

Ford Motor Company
I retired from Ford Motor Company in 1971. My retirement income is very low $392 per month pension and $1,022 per month Social Security, and that's it. Between health care cost of Medicare at $96.40, BlueCross at $386.90 and Humana at $23.30 and expensive medications I need, I barely have enough money left to stay alive. I'm also in the 'donut hole" for prescription drug cost and have had to pay full price for meds for three months now. June – Boca Raton, FL

GenCorp Inc.
In Jeannette, Pa., in early January, about 100 retirees of GenCorp Inc., formerly called General Tire & Rubber, met in a union hall to discuss the latest rise in their health-care premiums. The new cost of coverage for a couple was $568 a month. For most, this exceeded their company pensions. Because of the higher cost, many of the retirees at the meeting, whose ages hovered around 80, said they were dropping their employer's coverage.

Others don't dare drop it. Edward Peksa, who spent 24 years in GenCorp's tennis-ball department, said he needs the coverage to help pay for five drugs his wife, Anna, takes for arthritis, hypertension and thyroid and cholesterol problems. The couple's premium more than erases his GenCorp pension of $320 a month. To make ends meet, Mr. Peksa, 75, works 30 hours a week as a greeter at Wal-Mart Stores.

Drug Costs Threaten To Crack American Nest Eggs
Medical and drug expenses threaten to shatter the retirement nest egg - scrambling even the best-laid financial plans - according to a new nationwide survey of retirees, many of whom concede that their under-estimation of the impact of escalating health care costs has significantly compromised their "golden years" lifestyle.

One in three retirees claim that they are spending far more on their health care and prescription drugs than they expected, and 55 percent of retirees admit completely overlooking their health care and prescription drug needs when they were planning for retirement expenses, according to research released today by Medco Health Solutions, Inc.
Not only did a sizeable proportion of retirees fail to properly plan for health care and prescription drug costs, but nearly half of all retirees (49 percent) indicate they never assess the impact health care costs are having on their retirement savings or lifestyle.

The research was culled from "America's Unhealthy Nest Egg," a national survey of 1,000 Americans over age 65 conducted for Medco by Directive Analytics.

The Medco research revealed that for one in four middle-income retirees, $1 out of every $10 of their monthly retirement income goes to pay for medications alone. (**CNNMoney.com – 11/13/07**)

Medicare Drug Coverage Is Costing Most Seniors More - As if escalating prices for food and gas weren't enough of a worry, most seniors in Medicare's prescription-drug program are paying considerably higher monthly premiums for coverage this year, according to a study to be released today.

Those in the 10 largest plans -- which account for nearly three-fourths of seniors signed up for drug coverage -- are paying an average of $26.39 a month, or 16% more than last year, according to the analysis by Avalere Health, an information company serving the health care industry. “A 16% increase is significant in and of itself, because premiums are rising rapidly at a time when Medicare beneficiaries are finding it harder to afford it," said Dan Mendelson, president of Avalere. "These are individuals on a fixed income who are facing rapidly rising prices elsewhere in the economy." Of the top 10 plans, six raised their premiums, and four reduced them.

Average premiums for the most popular plan, AARP MedicareRx Preferred, rose by 15% to $32.08 a month, the study found. The plan, offered by UnitedHealth Group, has more than 2.7 million members. Premiums also rose for the next two most popular plans, Humana PDP Standard and Humana PDP Enhanced, by 69% and 6%, respectively. (**Los Angeles Times – 6/5/08**)

Drugs For Elderly More Costly - Drugmakers increased prices by an average of 7.4 percent last year for the brand-name medicines most commonly prescribed to the elderly, according to the advocacy group AARP. The increase far exceeded inflation, continuing a longtime trend.

AARP said prices charged to wholesalers have been slightly higher since the Medicare drug benefit started on Jan. 1, 2006. Since then, the outcry over prices has diminished, with the government picking up much of the tab.

"Unfortunately, many manufacturers have taken the absence of an outcry as a green light to go ahead and raise prices even more," said John Rother, AARP's policy director. (**The Washington Post – 3/5/08**)