



Prescription Drug Costs and Expenditures A Call For Action

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Executive Summary

The NRLN believes that taking immediate steps to implement the initiatives below will generate the sort of substantial and measurable 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 offset national health care reform costs and reduce out-of-pocket spending by American consumers. Savings of this magnitude will dampen health cost inflation and stimulate long-term economic growth for the U.S. economy.

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 of prescription drugs, as well as competitive bidding and robust formularies for Medicare Part D. Congress should also ensure that the FDA accelerate 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 might restrain competition among brand-name and generic manufacturers, such as “pay-for-delay” agreements that may keep lower-priced generic drugs off the market, must be further investigated and, if warranted, outlawed.

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The NRLN projects that if Congress acts to implement these initiatives, the nation's \$4,060 billion in projected prescription drug expenditures over the next ten (10) years can be reduced by 18%. This 18% savings would amount to \$730 billion:

<u>Recommended Initiatives</u>	<u>\$ Savings</u>	<u>% Savings</u>
Importation, Re-importation	\$203 billion	5%
Competitive Bidding	\$203 “	5%
Generic Drug Market Share Growth of 16%	\$243 “	6%
Elimination of Restraint if Trade Practices	<u>\$ 81</u> “	<u>2%</u>
TOTALS	\$730 “	18%

If the pledge of \$80 billion in savings by the Pharmaceutical Research and Manufacturers of America (PhRMA) in June of 2009 will close 50% of the Medicare D doughnut-hole, then Congress could allocate \$160 billion of this \$730 billion savings to pay for the virtual elimination of the doughnut hole. This would leave \$570 billion that could offset a substantial portion of the \$1 trillion or higher cost of national health care 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 reduce the deficit by \$160 billion over ten (10) years, and offset the total cost of U.S. health care by \$57 billion annually.

Prescription Drug Costs and Expenditures A Call For Action

I. The Prescription Drug Market and Retiree Demographics

According to the IMS Institute for Healthcare Informatics study released in April 2011, spending on prescriptions drugs in the U.S. in 2010 was \$307.4 billion, up from 300.3 billion in 2009. This is an increase of about \$60 billion since 2005 and \$135 billion since 2001. The volume of retail prescriptions dispensed totaled 4 billion, up from 3.2 billion dispensed in 2001. When adjusted for the estimated total population increase, real spending per capita increased from \$876 in 2006 to \$898 in 2010.

Chart: Spending on Medicines Reached \$307.4 Billion in 2010, Up 2.3% From 2009



The Use of Medicines in the United States: Review of 2010
 Report by the IMS Institute for Healthcare Informatics

Medicare Part D beneficiaries filled 871 million prescriptions in 2010, accounting for nearly 22% of all prescriptions filled. Part D accounted for approximately 11% of Medicare's \$523 billion budget in 2010.

According to the *Agency for Health Care Research and Quality*, the percentage of the U.S. population with a prescription drug expense in 2008 was 58% for those under age 65 and 90% for those 65 and older. These percentages changed little from 1997 when they were 59% and 86%, respectively.

The nation's approximately 79 million baby boomers (born 1946-1964) started turning 65 on January 1, 2011. According to the *U.S. Census Bureau*, the number of Americans age 45 or older totaled 118.4 million in 2010. Americans age 65 and older had the highest voter turnout with 70.3% voting in the national election in 2008, the Bureau's most current year for voting data. The next age group in terms of voting percentage was ages 45 to 64 where 69.2% of the Americans in this age range voted in the 2008 national election. 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.**

II. Prescription Drug Price Inflation and PhRMA'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 employers 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 percentage shown reflects the combination of the two responses "A Lot" or "Somewhat" with respect to what factors affect premium increases. Prescription drug costs had the greatest impact on health insurance premium 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 NRLN calculated the ten-year projected expenditures on prescription drugs, 2011 – 2020, starting with 2010 base year expenditures of \$307.4 billion and an assumed spending growth rate of 5% 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 \$4,060 billion.**

The Pharmaceutical Research and Manufacturers of America (PhRMA) promised during the health reform debate to reduce prices by a cumulative \$80 billion over ten (10) years would therefore yield savings equivalent to 1.97% of total prescription drug spending of \$4,060 billion over that same period, assuming a 5% annual compounding growth rate. This represents savings of less than 2% of total drug spending – and less than 1% of total U.S. health care spending. While PhRMA's gesture is significant, it's 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," more than validates the NRLN assumptions concerning health cost trends. HHS projected an 8.2% annual rate of increase in drug spending through 2017 and with total costs rising to \$515.7 billion in 2017, a 138% increase. **This data shows that the \$80 billion PhRMA promise amounts to a very minor 2.09% of total prescription drug spending, as projected by HHS.**

III. 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 exported to the U.S. Most American companies manufacture offshore and are therefore 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, while 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 January 20, 2009 article by Gardner Harris.

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. This places the American consumer in the position of having to pay excessive prices that effectively subsidize the lower prices that foreigners pay for drugs sold by U.S. companies.

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 would save U.S. consumers 5% of the more than \$4 trillion in total U.S. drug expenditures over the next ten (10) year period, a savings of \$203 billion.** 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.

IV. Competitive Bidding of Prescription Drugs

The Centers for Medicare and Medicaid Services (CMS) should be allowed to construct a robust Medicare Part 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 losses would cause significant premium increases. **In 2010, Medicare spent \$57 billion on prescription drugs, or 18.5% of the \$307.4 billion spent in the U.S. on prescription drugs.**

The NRLN estimates that competitive bidding would reduce prescription drug costs for combined Medicare and non-Medicare payments over the ten (10) year period by a minimum of 5% of \$4,060 billion, a potential savings of \$203 billion

If Medicare Part D's 18% share of the total market holds constant over the 10 years, the NRLN estimates Medicare would save $.18 \times \$203 = \36 billion. Non-Medicare savings would be $.82 \times \$203 = \167.4 billion.

V. 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.

Generics comprise the vast majority of prescriptions consumed, yet the FDA gives them a low priority. The May 2010 Kaiser Family Foundation report on *Prescription Drug Trends* reported that in 2008 22% of total prescription drug dollar sales, and 72% of total number of prescriptions dispensed, were for generic medicines. IMS Healthcare similarly reported in April 2011 that generics accounted for 78 percent of all retail prescriptions dispensed in 2010. The IMS report did not state the 2010 estimated sales value of these dispense generic prescriptions.

An April 2006 Federal Drug Administration (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, the seventeen (17) month approval interval suggests that it would take 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: **When two generic drugs compete with a brand drug, market prices drop 50%. When three generic drugs compete with a brand drug, market prices drop 75%. The FDA study didn't state savings for one-on-one competition, but it's safe to assume its 25% or more.**

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, a **54% increase over 2006**. **Some but not enough has changed to improve FDA efficiency or to reduce barriers to market entry of generic drugs since 2008.**

FDA paperwork and rules cause delays in the approval process and need to be revised or eliminated to achieve better efficiency and to afford more equitable treatment to generic manufacturers. Brand drug manufactures pay certain fees to the FDA that supplement the approval process budget for brand drugs. Generic manufacturers are not allowed to pay these fees. Rules are complicated and require that generic manufactures pay legal and other consulting fees in order to understand and comply with the meaning and intent of FDA rules.

The NRLN estimates that adequate FDA funding for generic drug approvals, improved approval efficiency and rule changes that create an even playing field for generic drug manufacturers would enable generic drug market share to be sixteen per cent (16%) higher over the next ten (10) years and would save ~ \$243 billion over ten years. This calculation is based on a conservative thirty-eight per cent (38%) savings estimate for every brand drug sales dollar displaced and assumes expenditures of \$4,060 billion over ten (10) years. Sixteen per cent (16%) share growth on \$4.060 billion = \$650 billion. Thirty-eight per cent (38%) savings on \$812 billion = ~ \$243 billion.

VI. 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 – sometimes called "pay-for-delay," "reverse payments," or "exclusion payment settlements" – keep generic drugs off the market that could be 75% less costly for consumers.** FTC officials say these deals violate anti-trusts laws, 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 current chairman.

Courts have been slow to declare such deals illegal. In two cases so far the FTC has tried to persuade the Supreme Court to hear the cases, to no avail. **While it is common for two companies to enter into a business agreement, these arrangements should not result in pricing arrangements, carving up markets or combining in a way that squeezes out smaller non-selected industry competitors. Selected generic company recipients of brand manufacturer financial support and counseling on how to weave through the FDA approval and market entry process, may gain an advantage over other generic manufacturers. The NRLN feels the net effect of pay-for-delay and other practices operate to the disadvantage of retirees and all consumers in the long run.**

Although hearings have been held, the NRLN wants Congress to review and broaden the scope of its evaluations to insure that retirees and all consumers are protected against artificial market and pricing constraints, and where warranted, to pass clear and enforceable anti-competitive legislation and or regulations. The NRLN speculates that **preventing anti-competitive practices could save 2% or \$81 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 in 2008 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 \$730 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 \$570 billion to help offset the costs of health care 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 a large amount of the cost of health care.

Appendix – Prescription Drug Cost Impact on Health and Disposable Income

A sampling of reports from individual retirees and media reports:

**From: Delbert Polad, St. George, UT
CenturyLink (Qwest) Retiree**

I am a member of AUSWR – the Association of U S WEST Retirees. For the last seven years I have had CML leukemia. There is no cure, but there is a standoff by taking a \$150 per day pill called Glevac, This amounts to \$4,500.00 per month. If I were to lose my health care benefits, I could not afford to pay for this daily treatment. To compound matters, my investments that my wife and I have lived off of have not done well , so we will soon be living off only Social Security. If we take any reductions on Social Security or Medicare, we don't know what we will do.

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**From: Mary Sheipline, West Bloomfield, MI
General Motors Retiree**

Because I MUST take brand name drugs (tier 2 and 3), I am paying more out of pocket. I hit the donut hole in June. My cancer medication didn't have a generic so it was \$500 out of pocket every 3 months.

###

**From: Ronald Herron, Lake Orion, MI
General Motors Retiree, Age 63**

Since my retirement, my employer-sponsored prescription, dental and vision coverage has been eliminated. I have already had to forego buying a prescribed medicine because the cost would devastate my monthly retirement budget. The high prices for prescription drugs have already changed the life my wife and I had expected to live in retirement.

###

**From: Richard Clark, Rochester Hills, MI
MichCon (DTE Energy) Retiree, Age 90**

I am 90 and my wife is 89. We currently have secondary health coverage and prescription drugs from my former employer. If I were to lose this coverage, we will have to discontinue our medication which would surely result in death in a short time. Without prescription drug coverage our meds would cost \$1,500 a month and who knows what health care would cost if available to us.

###

**From: Charlie Gray, Springwater, NY
Eastman Kodak Retiree**

My wife and I both have life threatening conditions. While we are not poor, we just discovered that the "doughnut hole" in Medicare Part D will affect us both in terms of what we can afford. Fortunately, we live within 100 miles from Canada. We are getting our passports and will travel once a month to Canada to purchase our medicines. Shouldn't be this way, and we're pissed!

###

From: Paula R. Brock, West Chester, OH
Chrysler Retiree

PLEASE...PLEASE...PLEASE do not let the government reduce Social Security and Medicare. I could not make it if this was to occur. Money is tight as it is now for us retired "oldies." By the time we buy our medicine, food, pay bills, etc., there just isn't anything much left.

###

From Claude Isnard, Pearland, TX
Alcatel-Lucent Retiree

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!

###

From Jim Marot, Parker, CO
Alcatel-Lucent 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.

Falling into Medicare Doughnut Hole Ups Nonadherence - Seniors caught in the Medicare Part D coverage gap known as the 'doughnut hole' are twice as likely to stop taking their medication, a new study found.

Between 11% and 14% of Medicare beneficiaries fall into the coverage gap each year and receive no financial assistance, wrote Jennifer Polinski, Sc.D, MPH, of Brigham and Women's Hospital Division of Pharmacoepidemiology, and colleagues in the Aug. 16 issue of PLoS Medicine.

The doughnut hole refers to a gap in Medicare Part D coverage that occurs when a beneficiary's total prescription costs are between \$2,800 and \$4,549 in a given year. During that gap, Medicare stops paying for drug costs, and the beneficiary must foot 100% of his or her prescription costs. Once drug spending tops \$4,549 (or when the year starts over) Medicare begins paying for drug cost once again. (*MedPage Today ~ Aug 16, 2011*)

CBO: Defunding healthcare law could end drug benefits - Permanently defunding the healthcare reform law could lead to the end of Medicare coverage for prescription drugs, according to the Congressional Budget Office.

Although the Medicare drug benefit predates healthcare reform, the new law made changes to the program — most notably eliminating the so-called “doughnut hole,” in which seniors must pay for their drugs out of pocket.

If the new healthcare law is defunded, the changes to the prescription drug program could not be implemented and Medicare would be unable to offer the benefit, CBO said.

CBO offered the new analysis in response to Rep. Henry Waxman (D-Calif.), who asked the budget office to analyze the impact of a permanent ban on funding for implementation of the new law.

A permanent ban on using appropriations to implement the law could prevent Medicare from signing contracts to administer the drug benefit, known as Medicare Part D. It also wouldn't be able to set rates for Medicare Advantage, so that program might also end. (*The Hill* ~ *May 26, 2011*)

Drug Lobby's Tax Filings Reveal Health Debate Role - It's official. The drug industry's chief lobbyists - the Pharmaceutical Research and Manufacturers of America - raised and spent at least \$101.2 million in 2009 on advocacy efforts during the contentious health care debate, according to IRS documents the group filed in mid-November.

Former PhRMA CEO Billy Tauzin says the lobby used the money - special contributions from member companies - for broadcast and print advertising, grassroots and direct lobbying, polling and consulting. Tauzin, who has a two-year contract to advise PhRMA's new leader, recently opened his own DC-based lobbying shop with his son Tom.

The former Republican Louisiana lawmaker was sweetly rewarded. He pulled down a \$2.1 million salary, as well as a bonus of \$2.3 million in 2009, according to the tax filing. Including other benefits, Tauzin's total compensation was \$4.6 million, just up from his \$4.4 million the year before.

Tauzin left PhRMA in mid-2010 amid rumors his support of the health overhaul led to his demise at PhRMA. (*Kaiser Health News* ~ *Dec 01, 2010*)

Drugmakers' 'Doughnut Hole' Deal to Shave Sales Less Than 1% - Drugmakers led by Pfizer Inc., AstraZeneca and Bristol-Myers Squibb Co. may provide more than \$2 billion in drug discounts to senior citizens next year under a deal pharmaceutical companies made with the White House, according to data compiled by Bloomberg.

Pfizer, the world's largest drug company, will cede less than half of 1 percent of its \$50 billion in annual revenue under the arrangement. The deal provides Medicare beneficiaries who fall into a coverage gap

known as the “doughnut hole” 50 percent off brand-name medications. Worldwide sales by brand-name drugmakers in 2008 totaled \$288 billion, according to data from the drug industry’s trade association.

“This was a good deal for pharma,” said Les Funtleyder, a health care analyst with New York-based Miller Tabak & Co. The data “disputes the narrative that health care reform is bad for pharmaceuticals, and as more data emerges I think you’re going to see that narrative play out across the health industry,” he said in a telephone interview.

The drug industry struck the deal with Democrats, who incorporated it into the health care overhaul President Barack Obama signed in March. In return for providing the price breaks and other concessions, pharmaceutical companies avoided policies such as allowing importation of drugs and having the government negotiate drug prices for Medicare beneficiaries.

Bloomberg compiled the data from a report released Sept. 24 by Medicare, the U.S. health program for the elderly and disabled.

Other Benefits

Drugmakers could make back some of the revenue they’re giving up through the discounts, Funtleyder said. Provisions in the law that expand insurance coverage will give brand-name pharmaceutical companies about 32 million potential new customers, according to Congressional Budget Office estimates.

Before the discounts were offered, Medicare beneficiaries who fell into the coverage gap often switched their brand-name drugs to generics or stopped taking medications altogether. The discounts make it more likely this group will continue taking brand-name drugs, Funtleyder said.

The doughnut hole is a feature of Medicare drug coverage that will gradually disappear during the health overhaul. Currently, Medicare pays for senior citizens’ drugs until the annual cost reaches \$2,830. The beneficiary at that point pays all costs until total out-of-pocket spending reaches \$4,550. Beyond that point, Medicare covers most costs.

Doughnut Hole

About 3.4 million people, or 14 percent of those who have Medicare drug plans, fell into the doughnut hole in 2007, the most recent year for which data is available, according to the nonprofit Kaiser Family Foundation in Washington.

Total spending by Medicare beneficiaries in the doughnut hole was \$4.9 billion in 2009, according to the Medicare data released last week. Assuming spending remains stable, drugmakers would wind up discounting about \$2.5 billion in 2011.

In 2009, New York-based Pfizer outpaced other drug manufacturers with beneficiaries who fell into the doughnut hole spending \$469 million on the company’s drugs. AstraZeneca, the London-based maker of cholesterol drug Crestor, was next, at \$400 million, followed by New York’s Bristol-Myers at \$368 million. AstraZeneca and Bristol-Myers, like Pfizer, have agreed to discount future such sales by half and

would likely give up less than 1 percent of product revenue to the discount program, according to their 2009 financial statements.

Drug Companies

Also among the top 10 companies whose drugs are used by Medicare beneficiaries in the doughnut hole are Ingelheim, Germany-based Boehringer Ingelheim at \$312 million; Novartis AG of Basel, Switzerland at \$303 million; London-based GlaxoSmithKline Plc at \$284 million; Merck & Co. of Whitehouse Station, New Jersey, at \$282 million; Indianapolis-based Eli Lilly & Co. at \$250 million; Eisai Co. of Tokyo at \$242 million; and Tokyo-based Takeda Pharmaceutical Co. at \$202 million. Those companies' drug sales made up 63 percent of all sales in the doughnut hole. Like Pfizer, they have agreed to offer a 50 percent discount.

The health law closes the Medicare drug coverage gap over a decade, first by giving \$250 rebate checks this year to people who reach the doughnut hole to reduce out-of-pocket expenses. It would continue reducing the amount beneficiaries pay by shrinking the coverage gap until the hole disappears entirely in 2020, according to the law. (*Bloomberg ~ Oct 01, 2010*)

US probes corruption in big pharma - The US Department of Justice is scrutinizing payments by leading pharmaceuticals companies for hospitality, consultants, licensing agreements and charitable donations in markets around the world as part of a wide-ranging corruption probe.

GlaxoSmithKline, Pfizer, Bristol-Myers Squibb and Eli Lilly, among others, have disclosed being contacted by the DoJ and Securities and Exchange Commission in connection with the investigation. Merck, the US drugs group, announced last week that it had also been contacted and was co-operating with investigators.

An industry attorney familiar with the probe said that the DoJ was looking at whether pharma companies had ignored a "systematic risk" inherent in the global drugs business and ignored obligations under local and US anti-bribery law.

The highly regulated nature of the business, combined with the fact that healthcare officials in many non-US markets were government funded, made the industry a natural target for such a probe, the person added.

The investigation is at a relatively early stage but is considered a priority for the DoJ.

While hospitality – including meals and all expenses-paid travel for conferences – has long been considered a potential risk for pharma groups, the DoJ's probe is looking at all aspects of companies' dealings in non-US markets, people familiar with the matter say. That includes the recruitment of physicians for clinical trials. In some markets, the same physicians may serve on regulatory boards that approve or deny drugs.

The DoJ declined to comment. But last November, Lanny Breuer, head of the DoJ's criminal division, announced that investigators would be focusing on international corruption in the pharmaceuticals industry for "years".

Mr Breuer warned a conference of pharmaceutical industry lawyers that prosecutors were gearing up for an investigation of international corruption in the sector. The drugs companies took notice.

That threat has now become a reality. Merck, AstraZeneca, Eli Lilly, Baxter, SciClone, and Bristol-Myers Squibb – have in recent months received inquiries from the DoJ and the Securities and Exchange Commission in connection with an industry-wide bribery investigation.

GlaxoSmithKline, the UK drugmaker, told the Financial Times on Thursday that it too had received "inquiries" from US authorities, but that it disclosed the issue "reactively" only to selected reporters in April.

Pfizer, the world's largest pharmaceutical group, said in February that it had voluntarily provided the DoJ and SEC with information concerning potentially improper payments outside the US and was exploring resolution of the matter.

There is perhaps no industry that is as vulnerable to violations of US anti-bribery laws than the pharmaceutical industry. In markets round the world, the companies deal, sometimes thousands of times in a single day, with doctors, clinicians, hospital operators and regulators who are considered under US law to be government officials, because they are employed by state-owned facilities.

Under the Foreign Corrupt Practices Act, the US anti-bribery law, companies may not offer items of value to foreign government officials for profit. One industry lawyer involved in the matter said global pharmaceutical companies operating in countries with state-run medical institutions deal with government officials at every turn of their business: whether it is seeking the go-ahead for a manufacturing site; obtaining drug licenses; conducting clinical trials; importing drugs; selling and marketing drugs to physicians; or getting a product on to a hospital's approved list.

"What most companies will find is that all of these areas are risky and, if they don't train and educate their people, they are going to find themselves with issues. For example, if you have hired customs brokers, how do you know they aren't bribing officials?" the attorney said.

According to the law firm Arnold & Porter, the DoJ is particularly interested in corrupt payments that may have influenced the reliability or integrity of data in clinical trials performed outside the US. A recent report by the Department of Health and Human Services found 80 per cent of marketing applications for drugs approved by the Food and Drug Administration in the US had relied on at least one foreign trial.

"Companies may find themselves facing critical legal issues if approval of products rested on the results of studies the DoJ deems corrupt," Arnold & Porter said in an advisory letter to clients last month.

A person familiar with the investigation confirmed that clinical trials were one of several areas the DoJ was examining.

Alexandra Wrage, the president of Trace, a non-profit organization that helps companies establish anti-corruption practices, said that alleged wrongdoing at pharmaceutical companies could often centre on inappropriately lavish hospitality, such as wining and dining doctors from state-run hospitals at conferences in Bali or Monaco.

“What we hear is not that doctors are expecting cash. But that doctors are only going to give companies time [for meetings] in front of a meal or a training session,” said Ms Wrage. Such sessions often involve all-expenses-paid travel.

In the US, drugs companies are also coming under more intense scrutiny for their interactions with doctors. Pfizer in April disclosed that it paid \$35m over six months to 4,500 doctors in private practice for education and the development and marketing of new drugs – payments that are legal in the US.

But legal experts familiar with the inquiries say they expect that the DoJ is examining egregious behavior that smells of bribery. (*The Financial Times ~ Aug 12, 2010*)

The gap in the closing of Medicare's drug ‘doughnut hole’ - Six years after Congress added a prescription drug benefit to Medicare, Democrats in the House and Senate are poised to make a central change that they and most older Americans have wanted all along: getting rid of a quirk that forces millions of elderly patients with especially high expenses for medicine to pay for much of it on their own.

The closing of an unusual gap in Medicare drug coverage -- a gap that Republicans had, when they controlled Capitol Hill and the White House, insisted was needed for the government to be able to afford the program -- would "forever end this indefensible injustice for American's seniors," Senate Majority Leader Harry M. Reid (D-Nev.) said in announcing that the Senate would join the House in supporting the change.

But details of the change underscore that, for patients and the federal budget alike, the implications of the sprawling health-care bills pushed through by congressional Democrats are more nuanced than lawmakers' talking points.

The Democrats and President Obama have been clear that the "doughnut hole," as the gap is known, would disappear gradually over the next 10 years. They have not mentioned that Medicare patients would, according to House figures, face a slightly larger hole in coverage during two of the next three years than they do today. (*Washington Post ~ Dec 28, 2009*)

Firms Warn of Cuts to Benefits - Some of the biggest employers in the U.S. are warning that a provision in the Senate's proposed health-care overhaul could lead to cuts in retiree benefits and a sharp reduction in reported earnings next year.

Companies including Boeing Co., Deere & Co., MetLife Inc. and Xerox Corp. plan to lobby Democratic leaders to drop the provision, which would change the tax status of payments for retiree health benefits.

Democrats identified the change as a way to help pay for the health-care overhaul. It would raise about \$5.4 billion over 10 years -- a relatively small slice of the bill's overall cost -- according to estimates.

The AFL-CIO has joined the corporate giants in an unusual alliance to warn the provision would encourage companies to drop drug benefits for millions of retirees.

One industry group estimated that as many as one-third of the companies providing the benefits could drop them to avoid the hit to earnings. Many of the companies that would be hardest hit are unionized and offer better retiree benefits than are available under Medicare.

Under the 2003 law that created a prescription-drug benefit known as Medicare Part D, companies that continued to provide such benefits on their own qualified for a 28% tax-free subsidy -- worth about \$600 a year per retiree. Hundreds of major companies took advantage of the provision and were able to list the subsidy on their balance sheets as a reduction to their retiree health liability.

But the Senate bill would tax the subsidy, dramatically increasing companies' tax liability for years. Under U.S. accounting rules, companies would be required to register the change as a loss in earnings -- all at once.

An analysis by the American Benefits Council, an advocacy group for large employers, found the tax change could result in a one-time 35% reduction in earnings for a typical company now receiving the subsidy. For companies with very large legacy plans as a result of multiple mergers, the impact could be more severe, say experts and company executives. Caterpillar Inc., another major company raising alarm over the provision, projected in its annual report that it expected to receive \$370 million in Part D subsidies between 2009 and 2018.

The chief financial officers of a dozen large U.S. corporations said the provision "would result in large earnings statement reductions" by requiring employers "to immediately account for the present value of this tax increase," according to a letter sent to Democratic leaders and the White House this month.

In a separate letter, the chief executives of AT&T Inc. and Verizon Communications Inc. warned "the change in tax treatment would prove to be a distraction to the capital markets, at a time of grave economic uncertainty."

Many big companies count this provision as their chief complaint with the Senate health-care bill.

"Proposed changes to the tax treatment of the retiree drug subsidy would punish companies that are doing the right thing by continuing to provide retiree prescription drug benefits," said Tim Elder, a spokesman at Caterpillar Inc.

Mr. Elder said the financial impact on Caterpillar would potentially cause the company "to re-evaluate continued coverage."

The tax on drug-benefit subsidies is expected to help pay for expanded coverage for uninsured people. The House bill includes a similar provision but would phase in the new tax gradually.

Opponents argue any revenue gains could prove illusory if companies all decide to shed their retiree drug coverage, thus pushing people onto Medicare Part D. Paying the companies a subsidy costs the

government roughly \$600 per person, while covering the retirees themselves would cost the government about \$1,900 each.

The American Benefits Council concluded that the provision would become a net revenue drain if just 24% of retirees are dropped from employer plans. About seven million retirees now receive their drug coverage through subsidized company payments, according to various estimates.

Ken Porter, an expert on the issue at the Benefits Council, said internal discussions among corporate members of the council indicated that about a third of the companies receiving the subsidy may choose to shed retiree drug plans before the bill becomes law.

"My sense is that you are going to see a lot of companies dump their retirees onto Medicare," said Tom Scully, a former Medicare administrator who helped create the drug benefit program. "I do not believe that the tax guys in Congress made the right calculation here." (*The Wall Street Journal* ~ Dec 24, 2009)

Auditors: Drug marketing falls short - About 85 percent of the marketing materials that private insurers use for their prescription drug plans fail to meet all of Medicare's guidelines for those products, federal auditors said Thursday.

The marketing products include enrollment applications for the Medicare drug benefit or explanations of a plan's benefits and rules. The Centers for Medicare and Medicaid Services has dozens of requirements for how the information is supposed to be presented to the elderly and disabled. Auditors found that the materials routinely violated one or more of those requirements.

"It's unconscionable that CMS has let the insurance industry's materials including essential items like pharmacy directories and summaries of benefits fail to properly inform seniors 85 percent of the time," said Sen. Max Baucus, D-Mont., chairman of the Senate Finance Committee. (*The Associated Press* ~ Sep 04, 2008)

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 ~ June 5, 2008*)

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. (*Washington Post ~ Mar 5, 2008*)

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 ~ Nov 13, 2007*)