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The Statin Drugs

Prescription and Price Trends
November 2004 to October 2005

and

Potential Cost Savings in Medicare from Increased Use of Lower-Cost Statins

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Executive Summary

The statins are among the most widely prescribed drugs in the U.S. They are used to treat elevated cholesterol and heart disease. In 2004, two statins – atorvastatin (Lipitor) and simvastatin (Zocor) – were the number one and number two best-selling drugs in the country and the statin class of drugs topped overall 2004 prescription drug sales. Statin use is expected to grow in the years ahead, driven in part by the new coverage provided under the Medicare drug benefit.

This study used a nationwide database to examine trends in prescriptions and the retail price of statins over the 12-month period from November 2004 to October 2005. It also projects potential savings in the Medicare program in 2007 from a switch to lower-cost generic statins from higher-cost statins.

The study's key findings are:

- Taxpayers, insurers, and Medicare beneficiaries would save **$8.2 billion** in 2007 alone if a concerted effort is made this year and next to shift statin users to lower-cost generic statins from higher-cost ones. The expected availability this summer of two more generic statins (lovastatin is the only one now) should make such savings highly achievable in 2007 and beyond. Such a magnitude of savings could yield more than a 50% reduction in total statin spending.

- Monthly prescriptions for statins rose 2.6%, from an average 11.3 million in the six month period November 2004 to April 2005 to 11.6 million per month in the six month period May 2005 to October 2005. (A six month time frame is used because the number of prescriptions fluctuates month to month.) Several statins experienced declining prescriptions, most notably Altoprev, Pravachol, and Lescol. Prescriptions for Lipitor were flat while those for Zocor declined somewhat. Crestor prescriptions rose slightly.

- Prescriptions for generic lovastatin increased 15.2%, a positive sign that doctors and payers are becoming more cost conscious. Generic lovastatin is the least costly statin.

- Prices rose modestly for most of the statins over the period examined. However, price increases exceeded general inflation (3.5%) for some of statins – notably Lipitor and Pravachol, up 5.8% and 7.2% respectively averaging all dose strengths. They also exceeded health care inflation which was 4.5% over the past year.

- The price for the most common doses of generic lovastatin declined an average 5.2%. Lovastatin was the only statin whose price declined.

Introduction

The class of drugs commonly known as statins are among the most widely prescribed drugs in the U.S. They are used to treat elevated cholesterol and heart disease. Statins are also prescribed for people with diabetes.

In 2004, two statins – atorvastatin (Lipitor) and simvastatin (Zocor) – were the number one and number two best-selling drugs in the country and the statin class of drugs topped 2004 overall prescription drug sales at $15.5 billion (6.6% of all drug sales). That was a 12% increase in statin sales over 2003 and up from $11 billion in 2001.[1] Lipitor was also the most widely prescribed drug in 2004 with 75 million prescriptions dispensed.

The rise in use primarily reflects the increasing numbers of people taking a statin, although people are taking statins for longer periods, too. In the latest long-term trend data available, just under 10% of U.S. residents aged 20 and older took a statin in 2002, up from 3% in 1994.[2] Use of statins among people age 65 and older is more common, and increased from 12% of that population in 1997 to 27% in 2002.[3]

Statin use has increased sharply in recent years because: (a) high cholesterol, heart disease, and diabetes are being diagnosed more frequently; (b) more evidence for their effectiveness and relative safety has emerged, (c) the indications for their use has expanded in recent years; (d) doctors have become more comfortable prescribing them; and (e) they have been widely promoted and advertised to both doctors and the public. For example, AstraZeneca spent $211 million advertising rosuvastatin (Crestor) to consumers in 2004. Pfizer spent $120 million advertising Lipitor.[4] Lipitor was widely advertised in 2005 as well, as was the newest statin-containing drug, Vytorin.

Surging sales revenue from statins is also attributable to their prices. Statins are not the most expensive drugs on the market, but they are not cheap either. Most cost between $2.50 and $5.00 for a single daily pill, which translates to $75 to $150 a month or $900 to $1,800 a year. One generic (lovastatin) is available and costs as little as $1 a day.

The increased use of statins has spurred controversy. Some doctors and public health advocates are concerned that too many people are turning to these drugs before trying to lower their levels of the "bad" (LDL or low density lipoprotein) cholesterol through dietary and lifestyle changes. Studies show that LDL cholesterol can be lowered (generally by 7% to 12%) by even modest reductions of saturated fat in the diet.

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[1] Data from IMS Health, Annual Report on prescription drug trends (Feb 14, 2005). www.imshealth.com. Accessed December 20, 2005.

[2] "Trends in Serum Lipids and Lipoproteins of Adults, 1960-2002," *Journal of the American Medical Association* (October 12, 2005),Vol. 294:1773-1781.

[3] "Trends in Statin Use in the Civilian Noninstitutionalized Medicare Population, 1997 and 2002," Statistical Brief #97, Agency for Healthcare Research and Quality (September 2005). Based on data from the Medicare Expenditure Panel Survey. www.ahrq.gov.

[4] "The New Face of Consumer Advertising," *Med Ad News* (June 2005).

Similarly, studies show that regular aerobic exercise helps raise blood levels of the "good" (HDL or high density lipoprotein) cholesterol by 10% to 15%.
Most doctors agree that all people who need to lower their LDL levels should modify their diets *whether or not they are prescribed a statin.* But there is no medical consensus on who should try to lower cholesterol initially by diet alone and who should start taking a statin (or other type of cholesterol-lowering drug) as initial therapy.

That said, data on population cholesterol levels, heart disease, diabetes and other conditions suggest that upwards of 40 to 50 million people in the U.S. could benefit from taking a statin, but only about 14 to 17 million are being actively treated.[5] Driving the increase in the estimated number of untreated and under-treated is clinical advice by heart disease experts and the government to lower LDL levels below targets set just a few years ago.[6] Studies of people with heart disease show that the lower the LDL level, the better.

Seven statins are available by prescription in the U.S. They are:

Generic Name	**Brand Names(s)**	**Available as a Prescription Generic Drug?**
Atorvastatin	Lipitor	No
Fluvastatin	Lescol, Lescol XL	No
Lovastatin	Mevacor, Altoprev	Yes
Pravastatin	Pravachol	No*
Simvastatin	Zocor	No*
Simvastatin/ ezetimibe	Vytorin	No
Rosuvastatin	Crestor	No

**Generic version expected in 2006.*

This report uses data from a large pharmaceutical sales database to examine trends in prescriptions and the retail price of statins over the 12-month period November 2004 to October 2005. It also uses that same data to calculate potential savings in Medicare and for Medicare beneficiaries from switching to lower-cost statins from higher-cost statins. These latter projections are highly relevant to the new Medicare prescription drug benefit, also known as Medicare Part D, since statins are expected to be one of the most prescribed types of drugs to seniors in the years ahead.

[5] "Trends in Serum Lipids and Lipoproteins of Adults, 1960-2002," *Journal of the American Medical Association* (October 12, 2005),Vol. 294:1773-1781. Also: The Bottle Report, Bear Stearns Research (October 31, 2005). Some recent analyses have even suggested that one-third, or 100 million, Americans, are potential candidates for treatment with a statin. See: Ma, J. et al,, "National Trends in Statin Use by Coronary Heart Disease Risk Category," PLOS (Public Library of Science) Medicine (May 2005) Volume 2, Issue 5.

[6] The National Cholesterol Education Program sponsored by the National Heart, Lung, and Blood Institute.

Methods

Data are for all U.S. prescriptions dispensed regardless of payer. The average monthly prices we present reflect retail prices paid in cash by consumers at neighborhood and chain pharmacies, and at the pharmacies in food and large discount stores. Thus, they do not include third party-paid drugs – such as those paid by commercial insurers and Medicaid – since such drugs often include bulk discounts and rebates that can lower the final transaction cost. The prices we present are also national averages and thus may differ from actual prices in different geographical markets in the U.S. The monthly costs are calculated based on a per pill cost that is averaged over varying prescription sizes (30-day, 60-day, 90-day, etc) and dosing regimens. The monthly cost is then calculated based on an average of 30.4 days a month.

The projections we calculate for statin use by Medicare beneficiaries make a number of assumptions which are presented in that section of this report.

The analysis in this report was conducted by Consumers Union and the *Consumer Reports Best Buy Drugs* project staff. It was not done in conjunction with Wolters Kluwer Health, whose Pharmaceutical Audit Suite (PHAST) database we used to determine retail cost and the number of prescriptions dispensed.

A separate report giving practical advice to consumers on the use of statins is being released at the same time as this analysis. The report is an update of one released in December 2004. It is available free at *Consumer Reports Best Buy Drugs* Web site, www.CRBestBuyDrugs.org.

Findings – Prescription and Price Trends

Prescription Trends

Despite calls from some quarters for increased use of statins and recent changes in clinical guidelines that favor their use, the rise in prescriptions for statins stalled somewhat in the 12-month period examined. Monthly prescriptions for statins rose only 2.6%, from 11.3 million in the six-month period from November 2004 to April 2005 to 11.6 million per month in the six-month period from May 2005 to October 2005. (A six-month time frame is used because the number of prescriptions fluctuates month to month.)

Several of the statins experienced declining prescriptions, most notably Altoprev, Pravachol, and Lescol. Prescriptions for Lipitor were flat while those for Zocor declined somewhat. Crestor prescriptions rose very slightly. (See Table 1.)

Table 1. Statin Prescription Trend – November 2004 to October 2005

Generic Name	Brand Name	Prescriptions Average Per Month, Nov. 2004 – April 2005[1]	Prescriptions Average Per Month, May 2005 – Oct. 2005[1]	Change in number of prescriptions[2] (%)
Atorvastatin	Liptor	5,900,000	5,900,000	0
Ezetimibe/Simvastatin[3]	Vytorin	397,000	818,000	+106%
Fluvastatin	Lescol	126,000	109,000	-13.5%
Fluvastatin	Lescol XL	229,000	217,000	-5.2%
Lovastatin	Altoprev	60,000	51,100	-14.8%
Lovastatin[4]	Lovastatin	752,200	866,600	+15.2%
Lovastatin	Mevacor	5,627	4,793	-14.8%
Pravastatin	Pravachol	1,000,000	897,000	-10.3%
Rosuvastatin	Crestor	702,500	706,200	+0.5%
Simvastatin	Zocor	2,150,000	2,050,000	-4.7%

Data source: Wolters Kluwer Health, a healthcare information company

1. Average of six months is calculated because prescriptions fluctuate from month to month.
2. Change is calculated base on average monthly prescriptions from first six month period to second six month period.
3. Combination of simvastatin and the drug ezetimibe. First entered the U.S. market in summer 2004.
4. This version is the generic.

The rapid growth in Vytorin prescriptions very likely came mostly at the expense of the other statins. That is, doctors may have switched their patients from other statins to Vytorin. Some part of Vytorin's growth may also have been due to new patients taking a statin for the first time.

Vytorin is the latest entry in the statin market. It was first sold in mid 2004. It is a potent cholesterol reducer on a par with Lipitor, Crestor, and Zocor. It offers a novel combination in this category – being a mix of simvastatin and a non-statin cholesterol reducer called ezetimibe (also marketed separately as Zetia). It is being heavily promoted in ads to doctors and consumers.

A portion of the loss of market share by Lescol, Pravachol, and Zocor may be attributable to a growth in prescriptions for generic lovastatin. Lovastatin is the oldest statin and the first to lose patent protection (in 2001). But despite its substantially lower price (See Table 2), its market share has lagged in large part because (1) it is a less potent LDL reducer and (2) it is no longer promoted to doctors or consumers.

Under current typical use, lovastatin is intended only for people who need less than a 30% or so reduction in their LDL and have no risk factors for heart disease (such as smoking, diabetes, and obesity). Lovastatin's gain in the period examined may

signal a heightened awareness among doctors of the utility of this less-costly medicine for the millions of people who need modest LDL reduction.

Some pharmaceutical market analysts speculate that the slow down in the growth of statin prescriptions reflects a natural "rest period" after several years of rapid growth. Most analysts predict a rebound in statin sales and use in 2006 and 2007 with the advent of the Medicare (Part D) drug benefit. Growth in sales revenue may be tempered somewhat, however, by the expected availability of generic pravastatin and simvastatin. Together, these two drugs accounted for one in four statin prescriptions in 2004. This is discussed further in the Medicare section below.

Price and Cost Trends

Prices rose modestly for most of the statins over the period examined. (See Table 2 on the next page.) However, the increases exceeded general inflation (3.5%) for some of statins (Lipitor and Pravachol, notably). They also exceeded healthcare inflation, which was 4.5% over the past year.[7]

Altoprev, a long-acting "branded generic" form of the generic drug lovastatin, had the steepest cost increase. Its price climbed an average 31% across three dosage strengths over the period examined. That may account in large part for the drop off in prescriptions for the drug (which is not widely prescribed anyway).

Generic lovastatin is a notable stand-out in terms of price change over the period examined. It is the only statin whose price declined; for the two most commonly used doses (20mg and 40mg), its price *declined* an average 5.2%. The cost for the far less-prescribed 10mg dose rose 22%, in contrast.[8] The most likely explanation for the decline is increased competition for market share among the several lovastatin generics. More intense negotiation by larger payers (Pharmacy Benefit Managers, or PBMs, and Medicaid programs) for better generic prices may also account for the decline; such pressure influences retail cash-only price in the generic marketplace.

This is a positive development. Doctors concur that lovastatin is a viable choice for the millions of statin users who need relatively modest reduction in their LDL levels and who don't have heart disease or risk factors for heart disease. It is also a positive development for cash-paying statin users – for example, the uninsured – who may have trouble affording more expensive brand-name statins. At a cost of $1 to $1.88 a day, lovastatin is the most affordable statin. And it's likely to remain so throughout 2006 and into 2007 even as generic versions of Pravachol and Zocor become available. That's because prices for new generics are usually higher, especially if their initial generic manufacturers have six months of exclusivity under federal law.

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[7] Inflation data (Consumer Price Index) from Bureau of Labor Statistics, www.bls.gov/news.release/pdf/cpi.pdf. Accessed December 22, 2005.

[8] Like most statins, lovastatin tablets (except time-release tablets) can be split in half. This can decrease the price to the patient. A 10mg dose can be achieved by splitting 20mg, making the effective price of the 10mg dose well under $1 a day.

Table 2. Statin Price Trends – November 2004 to October 2005

Generic Name and Dose Strength	Brand Name	Average Monthly Cost November 2004	Average Monthly Cost - October 2005	Percent Change
Atorvastatin 10mg	Lipitor	$80	$85	6.3%
Atorvastatin 20mg	Lipitor	$117	$123	5.1%
Atorvastatin 40mg	Lipitor	$117	$124	6.0%
Atorvastatin 80mg	Lipitor	$117	$123	5.1%
Ezetimibe/Simvastatin 10mg-10mg	Vytorin	$93	$95	2.2%
Ezetimibe/Simvastatin 10mg-20mg	Vytorin	$95	$95	0%
Ezetimibe/Simvastatin 10mg-40mg	Vytorin	$95	$95	0%
Ezetimibe/Simvastatin 10mg-80mg	Vytorin	$94	$98	4.3%
Fluvastatin 20mg	Lescol	$64	$69	7.8%
Fluvastatin 40mg	Lescol	$64	$67	4.7%
Fluvastatin 80mg	Lescol	$82	$89	8.5%
Lovastatin 20 mg	Altoprev	$77	$98	27.3%
Lovastatin 40mg	Altoprev	$78	$101	29.5%
Lovastatin 60mg	Altoprev	$79	$107	35.4%
Lovastatin 10mg	Lovastatin	$27	$33	22.2%
Lovastatin 20mg	Lovastatin	$39	$37	-5.1%
Lovastatin 40mg	Lovastatin	$60	$57	-5.0%
Lovastatin 10mg	Mevacor	$47	$43	-8.5%
Lovastatin 20mg	Mevacor	$80	$83	3.8%
Lovastatin 40mg	Mevacor	$147	$148	0.7%
Pravastatin 10mg	Pravachol	$102	$110	7.8%
Pravastatin 20mg	Pravachol	$101	$108	6.9%
Pravastatin 40mg	Pravachol	$151	$162	7.3%
Pravastatin 80mg	Pravachol	$149	$159	6.7%
Rosuvastatin 5 mg	Crestor	$93	$101	8.6%
Rosuvastatin 10 mg	Crestor	$92	$99	7.6%
Rosuvastatin 20 mg	Crestor	$91	$97	6.6%
Rosuvastatin 40 mg	Crestor	$90	$95	5.6%
Simvastatin 5mg	Zocor	$65	$69	6.2%
Simvastatin 10mg	Zocor	$85	$87	2.4%
Simvastatin 20mg	Zocor	$149	$154	3.4%
Simvastatin 40mg	Zocor	$149	$154	3.4%
Simvastatin 80mg	Zocor	$145	$154	6.2%

Data source: Wolters Kluwer Health, a healthcare information company

Potential Savings in the Medicare Program – 2007and Beyond

The new Medicare drug benefit that began in January 2006 is projected to cost taxpayers an estimated $750 billion over the next decade. Medicare beneficiaries will spend an additional $1.2 trillion on prescription drugs out of their own pockets between now and 2016 (as the benefit is currently designed). Statin drugs alone may account for 11% of the total drug expenditure for this population from 2006 to 2015, or $215 billion.[9] In 2007, we project an expenditures on statins for and by Medicare beneficiaries of $14 billion, absent changes in the mix of statins prescribed (such as those discussed in this analysis).[10]

As a result, we and other pharmaceutical market analysts predict an intense effort to restrain the potential sharp cost and utilization growth in this class of drugs. There are only two ways to do that: (1) negotiate deeper price discounts and (2) switch users to less costly but equally effective medicines.

We have calculated the potential savings to Medicare in 2007 if millions of Medicare beneficiaries were switched to effective lower-cost statins from higher-cost statins, and particularly to lower-cost generic lovastatin and simvastatin. Lovastatin is available as a generic drug now. It is a *Consumer Reports Best Buy Drug* in the statin class, for people who need modest (less than 30%) LDL lowering. Simvastatin, now sold only as brand name Zocor, is expected to lose patent protection in the summer of 2006 and become available as a generic almost immediately. Pravastatin (Pravachol) is also expected to lose patient protection in 2006. For simplicity, we use only lovastatin and simvastatin in this analysis.

We also present, for purposes of comparison, the potential savings if current VA (Department of Veterans Affairs) negotiated prices were paid for the brand-name drugs used in our analysis. Recent studies indicate that the VA often obtains the best price in the nation for many commonly used medicines. Congress is very likely to measure prices paid by Medicare drug benefit plans against the VA negotiated prices over the next few years.

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[9] The statin drugs in 2004 accounted for 6.6% ($15.5 billion) of total outpatient U.S. prescription drug spending, according to IMS Health. See footnote 1. Almost three times as many older Americans take statins as do people aged 20 to 64. We therefore have assumed an 11% share of total drug spending on statins in the Medicare program. In making that projection, we assume steady growth in the use of statins and statin-containing drugs (including new ones) over the period 2006 to 2016, balanced by the availability of less expensive generic versions of several statins and aggressive efforts to restrain the growth in statin prices, both brand and generic. We project total out-of-pocket costs for Medicare Part D enrollees at $600 billion over the decade 2006-2015, based on estimates by the Congressional Budget Office (CBO). We project drug costs for non-enrollees at an additional $600 billion, also based on CBO estimates. If more enroll, the change in total spending is not dramatically affected, but would be higher. See: *A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit*, July 2004 (www.cbo.gov, accessed January 2, 2006).

[10] If statin sales increase 8% a year between 2004 and 2007, statin expenditures for the U.S. population will be around $19.5 billion in 2007. We estimate that 72% of that will be for and by Medicare beneficiaries.

Our results are presented in Tables 3 and 4 below. We make a number of important assumptions, the bases for which are further explained in footnotes. They are:

(1) 12 million Medicare beneficiaries will take a statin in 2007.[11]

(2) 6 million will need modest LDL cholesterol reduction and 6 million will need more substantial LDL reduction.[12]

(3) No change in statin prices in 2007 compared to today.[13]

(4) All those who need modest LDL reduction shift to lovastatin; 100% of those taking Zocor switch to generic simvastatin as do 50% of those taking other potent statins (such as Lipitor and Crestor).[14]

(5) A 20% discount off the retail (cash-paying) price used in this analysis.[15]

(6) Generic simvastatin at a price one-fourth the current Zocor price.[16]

Table 3 on the next page presents results for 6 million Medicare beneficiaries who need modest LDL reduction and who are not at identifiable elevated risk for heart disease, heart attack, or stroke. For simplicity, this table compares only Lipitor to generic lovastatin. In the real world, of course, people take five other statins besides Lipitor at a range of prices. That said, Lipitor dominates the statin market. The key finding is *an estimated savings of **$4.9 billion** in 2007 if all the Lipitor users were switched to generic lovastatin,* with both drugs priced at a 20% discount to prevailing prices today. Again, we reiterate, in most cases there is no reason that a person with modestly elevated LDL who is not at risk of heart disease needs to take a potent statin such as Lipitor.[17]

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[11] 11 million Medicare beneficiaries took a statin in 2002, the last year for which data exist. So we consider 12 million a conservative estimate for 2007. "Trends in Statin Use in the Civilian Noninstitutionalized Medicare Population, 1997 and 2002," Statistical Brief #97, Agency for Healthcare Research and Quality (September 2005). Based on data from the Medicare Expenditure Panel Survey. www.ahrq.gov. Accessed December 23, 2005.

[12] Modest reduction means less than 30% -- for example from 150mg/dl to 105mg/dl. More substantial means 30% or more lowering in LDL levels. People in this latter category may also need a more potent statin because they have heart disease, cerebrovascular disease or diabetes, or are at high risk of heart disease. See the *Consumer Reports Best Buy Drugs* statin report at www.CRBestBuyDrugs.org.

[13] We do this for simplicity. Individual drug prices may well rise but projecting how much is difficult. Assuming static prices does not change the outcome of our analysis and calculation of potential savings.

[14] A 100% switch would not happen in the real world. But recent generics have gained high percentages of users in a relatively short time – on the order of 75% to 95%. We believe there will be strong cost pressure to shift not only all Zocor users to generic simvastatin, but many Lipitor, Crestor and Vytorin users.

[15] We believe it's reasonable to assume that the new private Medicare drug plan insurers will achieve at least a 20% discount off current retail prices for statins. It's possible the discounts will be deeper.

[16] Most generics cost one fifth to one third the price of the brand they copy after about a year of generic availability. We assume, again, price pressure in the statin market beginning in mid-2006.

[17] This does not constitute medical advice. All people should consult their doctors about their individual medical needs.

Were the Medicare program able to benefit from the VA discount currently available, taxpayers, health plans and Medicare beneficiaries would save **$2.3 billion** if Lipitor users stayed Lipitor users and **$6.2 billion** if they were shifted to lovastatin.

Table 3: Projected Savings 2007 – 6 Million Lower-Risk Medicare Statin Users *(Those Needing Modest Cholesterol Reduction)*

		Cost Per Month and Year[1]	**Total Cost Per Year if 6 Million Statin Users Took This Drug**	**Annual Potential Savings if *All* Switched or if Purchased at VA Price:**
Brand Drug Often Prescribed	Lipitor 20mg	$98 a month $1,176 a year	$7.1 billion	
VA Price for Drug Often Prescribed[2]	Lipitor 20mg	$66 a month $792 a year	$4.8 billion	$2.3 billion
Lower Cost Alternative	Lovastatin 20mg	$30 a month $360 a year	$2.2 billion	$4.9 billion
VA price, Alternative[3]	Lovastatin 20mg	$12 a month $144 a year	$864 million	$6.2 billion

1. Based on average monthly cost October 2005, from NDCHealth, with 20% discount calculated except for VA prices
2. VA price from *Falling Short: Medicare Prescription Drug Plans Offer Meager Savings*, Families USA, December 2005. A pharmacy dispensing fee of $4.00 is added because the VA price is wholesale.
3. Price as of January 5, 2006. Provided by VA staff. A pharmacy dispensing fee of $4.00 is added because the VA price is wholesale.

Table 4 below presents results for the projected 6 million Medicare beneficiaries in 2007 who will need more substantial cholesterol reduction or who are at high risk of heart disease (or have heart disease) and thus would be clinically advised to take a more potent statin. We assume a 100% shift from Zocor to generic simvastatin (there's no reason not to, and Medicare drug plans will push this hard) and a 50% switch from other statins to generic simvastatin. This latter assumption factors in possible resistance from doctors to switch users of one potent statin to another if their patient is doing well on the drug they are taking. This is common in medicine and has clinical roots in the belief among physicians that patients respond differently to individual drugs.

The key finding in Table 4 is that if *all* Zocor users were switched to simvastatin in 2007 and 50% of users of Lipitor and other statins were switched to generic simvastatin, *a **$3.3 billion** savings for taxpayers, health plans, and beneficiaries would be achieved.*

Were the Medicare program able to benefit from the VA discounts currently available, taxpayers, health plans and Medicare beneficiaries would save between **$1.1 billion** and **$2.5 billion** if all were switched to Lipitor and **$4.1 billion** and **$5.5 billion** if all were switched to Zocor. The VA has negotiated an unusually deep discount on Zocor – at $20

a month. (We add in a $4.00 dispensing fee.) This is likely a concession by Zocor's maker (Merck) to achieve preferred drug status in the VA program and as a prelude to generic simvastatin in the summer of 2006. At this price, the VA program would have little motivation to switch to generic simvastatin unless its price was to fall below $20 to $25 a month.

Table 4: Projected Savings 2007 – 6 Million Higher-Risk Medicare Statin Users
(Those Needing More Substantial Cholesterol Reduction)

		Cost Per Month and Year[1]	**Total Cost Per Year if 6 Million Used This Drug**	**Annual Projected Savings if Switch to Lower-Cost Drug**
Brand Name Drug often Prescribed	Zocor 20mg	$122 a month $1,459 a year	$8.8 billion	
Brand Name Drug Often Prescribed	Lipitor 20mg	$98 a month $1,181 a year	$7.1 billion	
Brand Name Drug Often Prescribed[2]	Other statins	$80 a month $960 a year	$5.8 billion	
VA price for Lipitor[3]	Lipitor 20mg	$66 a month $792 a year	$4.7 billion	$1.1 billion to $2.5 billion[3]
VA Price of Zocor[4]	Zocor 20mg	$24 a month $288 a year	$1.7 billion	$4.0 billion to $5.5 billion[5]
Generic Simvastatin[6]	Simvastatin 20mg	$31 a month $372 a year	$2.2 billion	$3.3 billion[6]

1. Based on average monthly cost October 2005 from NDCHealth with 20% discount calculated except for VA price.
2. Vytorin, Crestor, Lescol, etc. Assume an average discounted price of $80 a month.
3. Savings range calculated from low of $5.8B to average of $7.2 B ($5.8+7.1+$8.8 billion divided by 3). A pharmacy dispensing fee of $4.00 is added because the VA price is wholesale.
4. This is an unusually low discounted price, likely a concession by Zocor's maker (Merck) to achieve preferred drug status in the VA program and as a prelude to generic simvastatin in June or July 2006. A pharmacy dispensing fee of $4.00 is added because the VA price is wholesale.
5. Savings range calculated from low of $5.8B to average of $7.2 B ($5.8+7.1+$8.8 billion divided by 3).
6. Assumes simvastatin will be one quarter the price of Zocor today, as discounted in row one. Projected savings for switch to generic simvastatin calculated as follows: 100% of Zocor users switch to simvastatin as do 50% of Lipitor and 50% of all other statin users in 2007. Lipitor currently has 50% of the statin market, Zocor 25% and the rest 25%.

Adding the potential savings in 2007 for the two groups of Medicare statin users (Tables 3 and 4) yields a total of **$8.2 billion** – $4.9 billion for those who need modest LDL

reduction and $3.3 billion for those who need more potent statins.[18] The context for this number is discussed below.

Conclusion and Discussion

The market for statins in the U.S. is currently in flux as (a) doctors choose from among seven competing drugs, one new; (b) consumers become increasingly aware of statins through direct-to-consumer drug ads; (c) payers pressure drug companies and pharmacies to reduce statin prices or grant discounts and rebates; and (d) everyone awaits the availability of the first generic versions of Zocor and Pravachol in 2006.

Despite expanded indications and broad acceptance of statins, growth in their use seems to have stalled somewhat in 2005. Several statins experienced a decline in prescriptions in 2005. That may be due to a "breather" after more than six years of substantial growth in the use and sales of statins. It could also be due to more caution by doctors in prescribing the drugs, under pressure from insurers or in the wake of safety concerns raised about Crestor in late 2004 and early 2005.

Companies that make and market statins appear to be holding the line on price increases, under pressure from payers to do so as statin expenditures soared over the last decade and as several statins took their place among the nation's best-selling and most widely prescribed drugs.

A 15% rise in prescriptions for generic lovastatin (and a slight decrease in its price) may signal growing concern about brand-name statin prices and more willingness by doctors to use this lower-cost statin instead of more expensive brands. Several managed care plans now ask network doctors to try lovastatin or a lower-cost preferred brand (a lower price for which has been negotiated) in some patients first before prescribing a brand-name non-preferred statin. At Kaiser Permanente in California, for example, fewer than 10% of patients on cholesterol-lowering drugs take Lipitor,[19] compared to around 50% nationwide.

The use and price of statins will be front and center as the Medicare drug benefit gets underway this year – because statins may well be the most expensive overall category of drugs in the program.

This report has ventured a projection of possible savings to taxpayers, insurers, and Medicare beneficiaries if doctors, drug plan sponsors, and beneficiaries themselves moved aggressively to switch to lower-cost statins when clinically acceptable. Based on assumptions we believe are reasonable and in some cases conservative, we have calculated a potential savings of **$8.2 billion** in one year alone (2007) if Medicare beneficiaries are prescribed effective lower-cost statins (two generics) versus higher-costs brand statins.

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[18] $8.2 billion is a future projection based on assumptions of drug use and price.

[19] Scott Hensley, "As Generics Pummel Its Drugs, Pfizer Faces Uncertain Future," *Wall Street Journal* (January 5, 2006), page 1.

This number is by definition a hypothetical projection resulting from assumptions about the number of beneficiaries who will take statins in 2007 (12 million) and the costs for the drugs. But we believe it strongly suggests and approximates the magnitude of savings achievable in the program. For example, we project that "real world" expenditures on statins for Medicare beneficiaries will be around $14 billion in 2007.[20] A reduction of total statin expenditures by $8.2 billion to $5.8 billion would thus represent a 58% savings in that one year.[21]

If the new drug benefit is going to be sustainable, this magnitude of savings is not an option. It is a requirement. Switching to lower-cost drugs where clinically appropriate will be one critical strategy in lowering program costs and out-of-pocket expenses for Medicare beneficiaries.

Finally, failure to constrain costs in Medicare Part D as currently designed will compel lawmakers to look at alternatives. We have included VA prices in our analysis to show the magnitude of savings that this government health program is already achieving through price negotiation and bulk purchasing.

[20] See foot note 10.

[21] Since we anticipate dynamic statin market changes in 2007 and beyond, calculation of a 5-year or 10-year "reduction" in statin expenditures is problematic. For example, Lipitor is due to lose patent protection in 2011. However, at the same time, intensive research is underway on new statins and statin combination drugs (and other cholesterol-lowering or coronary-plague reducing drugs) that *could* in the long run offset the overall savings opportunity to be presented this year and next by the availability of generic versions of Zocor and Pravachol. An analogy would be the marketplace for high blood pressure drugs. Old line drugs such as diuretics and beta blockers are now available as inexpensive generics. But drug makers have continuously developed newer brand-name blood pressure medicines that they aggressively promote to doctors and consumers. Over the last decade, these drugs have tended to repress the potential savings from the wider use of the generics.