The Statin Drugs

Prescription and Price Trends
October 2005 to December 2006

February 2007
Executive Summary

The statin drugs are among the most widely prescribed in the U.S. They are used primarily to treat elevated cholesterol and heart disease.

Statin use has soared over the last decade, and is expected to continue to increase in the years ahead, driven in part by new drug coverage provided to Medicare beneficiaries (Medicare Part D).

This analysis uses a nationwide prescription drug database to examine trends in prescriptions and the retail prices of statins over the 15-month period from October 2005 to December 2006. The analysis divides that period in two – October 2005 to May 2006 and June 2006 to December 2006 – because prescriptions and prices fluctuate month to month and because two new generics became available in mid-2006.

Key findings:

- Monthly prescriptions for statins rose 3.9%, from an average 12.6 million per month in the period October 2005 to May 2006 to an average 13.1 million per month in the period June 2006 to December 2006 – a gain of some 500,000 prescriptions per month.

- Prescriptions for two new generic statins – pravastatin and simvastatin – soared, as anticipated, in the latter half of 2006, and simvastatin helped fuel the rise in prescriptions. The drugs are the generic versions of Pravachol and Zocor, respectively, both of which lost patent protection in 2006. The shift suggests aggressive moves by doctors, insurers, pharmacy benefit managers, pharmacists, and consumers to use the new generics – as was forecast.

- By December 2006, simvastatin had garnered 2.5 million prescriptions – 200,000 to 300,000 more than Zocor was averaging in the months prior to its patent loss.

- Despite the uptake of these new generics, however, brand-name statins retained a high market share with 71% of all statin prescriptions. Lipitor alone accounted for an average 43% of all statin prescriptions in the latter half of 2006, down slightly from 46% in the earlier period, but still substantial.

- Prices rose modestly for most of the statins over the period examined, and were in line with both general and health care inflation in 2006. This was due primarily to price competition and pressure from payers on statin prices. Both these forces are likely to intensify in 2007. Our data show prices for pravastatin and simvastatin before multiple generic versions of either were approved in late 2006. The price for both generics is widely expected to decline in 2007.
Introduction

The group of medicines known as “statins” are used to treat elevated cholesterol and heart disease. They are also prescribed to treat people who have diabetes and those who have had a stroke.

In 2005, one of the statin drugs – Lipitor – was the most prescribed drug in the country and statins were the top-selling class of drugs with $16 billion in U.S. sales (144.5 million prescriptions), up 28% from $12.5 billion in sales in 2002.1

This rise in use primarily reflects the increasing numbers of people taking a statin, although people are taking statins for longer periods, too. The latest long-term trend data available shows that 10% of U.S. residents aged 20 and older took a statin in 2002, up from 3% in 1994.2 Statin use among people age 65 and older is far more common, and more than doubled to 27% of that population in 2003 from 12% in 1997.3

Statin use has increased in recent years because: (a) high cholesterol, heart disease, and diabetes are being diagnosed more frequently; (b) more evidence supporting the effectiveness and relative safety of statins has emerged, (c) the indications for their use has expanded; (d) doctors have become more comfortable prescribing statins; and (e) they have been widely promoted and advertised to both doctors and the public.4

Not everyone applauds the increase. Some doctors and public health advocates are concerned that too many people are turning to these medicines before trying to bring their cholesterol down through diet and lifestyle. Studies show that “bad” (LDL – low density lipoprotein) cholesterol can be lowered by 7% to 12% through even modest reductions of saturated fat in the diet. 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

1 Data from IMS Health, Annual Report on prescription drug trends (Feb 20, 2006). www.imshealth.com. Data for 2006 from this source is not yet available, but will be soon.
4 The cost of consumer ads for statins are on a par with some of the more widely advertised products, such as cars, soft drinks and fast food. Three statins were among the top 20 most advertised drugs (to consumers) in the period Jan. 2005 to Nov. 2006. Crestor: $313 million. Vytorin: $274 million. Lipitor: $210 million.
taking a statin, but only about 20 million are being actively treated.\textsuperscript{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.\textsuperscript{6}

Six statins drugs are available in the U.S. One other medicine combines a statin with another type of cholesterol-lowering medicine. The seven drugs are:

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Names(s)</th>
<th>Available as a Prescription Generic Drug?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atorvastatin</td>
<td>Lipitor</td>
<td>No</td>
</tr>
<tr>
<td>Fluvastatin</td>
<td>Lescol, Lescol XL</td>
<td>No</td>
</tr>
<tr>
<td>Lovastatin</td>
<td>Mevacor, Altoprev</td>
<td>Yes</td>
</tr>
<tr>
<td>Pravastatin</td>
<td>Pravachol</td>
<td>Yes</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>Zocor</td>
<td>Yes</td>
</tr>
<tr>
<td>Simvastatin/ezetimibe</td>
<td>Vytorin</td>
<td>No</td>
</tr>
<tr>
<td>Rosuvastatin</td>
<td>Crestor</td>
<td>No</td>
</tr>
</tbody>
</table>

Notably, three statins are now available as lower-cost generics. Lovastatin has been a generic since 2001. Pravastatin became available in generic form in May 2006 and Simvastatin in July 2006, when the drugs Pravachol and Zocor, respectively, lost patent protection.

These two new generics have dramatically altered the statin marketplace and present a significant opportunity for cost savings for government, employers, insurers, and consumers. In particular, generic simvastatin is the most potent statin to become available as a generic. Potent statins, also which include Lipitor, Crestor, and Vytorin, lower bad cholesterol more substantially.

The availability of pravastatin and simvastatin present the federal government with an opportunity to substantially reduce taxpayer-subsidized costs in the new Medicare Part D prescription drug program.

This report uses data from a large pharmaceutical sales database to examine trends in prescriptions and the retail price of statins over the 15-month period October 2005 to December 2006.

A future analysis by \textit{Consumer Reports Best Buy Drugs} will estimate savings in the treatment of Medicare beneficiaries through 2009 from a shift to greater use of generic statins.


\textsuperscript{6} The National Cholesterol Education Program, National Heart, Lung, and Blood Institute. \textit{Circulation} (July 13, 2004); Vol. 110, pages 227-239.
**Methods**

Data are for all U.S. prescriptions dispensed regardless of payer. The average monthly costs 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 factor in the cost-basis of third party-paid drugs – such as those paid by commercial insurers, Medicaid, and Medicare Part D. Drug payment through these channels includes volume 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.). The monthly cost is then calculated based on an average of 30.4 days a month.

Prescription and price trends are analyzed in terms of averages per month from October 2005 to December 2006, with two periods delineated: the eight months from October 2005 to May 2006 and the seven months from June 2006 to December 2006. Two aggregate periods are chosen for the analysis because the number of prescriptions fluctuates month to month. Prices may also fluctuate.

In addition, the two time periods reflect the approximate division of the statin market into one in which only one generic was available (prior to May/June 2006) and one in which three generics were available, including simvastatin (June to Dec. 2006).

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.

A separate report comparing the effectiveness of the seven drugs, and giving practical advice to consumers on assessing their need for a statin and choosing one, can be obtained free at [www.CRBestBuyDrugs.org](http://www.CRBestBuyDrugs.org).

**Findings – Statin Prescription Trend**

Monthly prescriptions for statins rose 3.9%, from an average 12.6 million per month in the period October 2005 to May 2006 to an average 13.1 million per month in the period June 2006 to December 2006 – a gain of some 500,000 prescriptions per month.

Since November 2004, monthly prescriptions for statins have increased about 6.6%, or an average of about 1.5 million per month.

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7 Data from 2005 released in a January 2006 study, available at [www.CRBestBuyDrugs.org/PDFs/StatinAnalysis.pdf](http://www.CRBestBuyDrugs.org/PDFs/StatinAnalysis.pdf).
Table 1 on the next page presents the trend for each statin drug, with data for both brands and generics. As anticipated, Pravachol and Zocor lost their market share to the new generics. The shift occurred swiftly. By December 2006, Zocor prescriptions had declined to 371,000, from a high of 2.4 million in May 2006. Pravachol prescriptions declined to 133,300 in December 2006, from a high of 858,000 in October 2005.

The generics of both drugs picked-up most of the loss, suggesting direct shifts in prescriptions (from brand to generic) by doctors, insurers, pharmacy benefit managers, and pharmacists. Indeed, by December 2006, simvastatin garnered 2.5 million prescriptions – 200,000 to 300,000 more than Zocor was averaging in the months prior to loss of its patent.

A portion of those new simvastatin prescriptions likely came at the expense of the declining prescriptions for Lipitor, Lescol, and Altoprev. Lipitor alone lost an average 216,000 prescriptions per month between the two periods. Some of simvastatin’s pick-up may also have come from a shift of Pravachol to simvastatin.

Table 1. Statin Prescription Trend – October 2005 to December 2006

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Prescriptions Average Per Month, Oct. 2005 – May 2006¹</th>
<th>Prescriptions Average Per Month, Jun. 2006 – Dec. 2006¹</th>
<th>Change in Number of Prescriptions² (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atorvastatin</td>
<td>Liptor</td>
<td>5,841,000</td>
<td>5,625,000</td>
<td>-3.7%</td>
</tr>
<tr>
<td>Ezetimibe/Simvastatin³</td>
<td>Vytorin</td>
<td>1,183,000</td>
<td>1,487,000</td>
<td>+25.7%</td>
</tr>
<tr>
<td>Fluvastatin</td>
<td>Lescol</td>
<td>94,000</td>
<td>75,000</td>
<td>-20.7%</td>
</tr>
<tr>
<td>Fluvastatin</td>
<td>Lescol XL</td>
<td>199,000</td>
<td>164,000</td>
<td>-17.6%</td>
</tr>
<tr>
<td>Lovastatin</td>
<td>Altoprev</td>
<td>44,000</td>
<td>34,000</td>
<td>-22.9%</td>
</tr>
<tr>
<td>Lovastatin⁴</td>
<td>Generic</td>
<td>1,051,000</td>
<td>1,197,000</td>
<td>+13.9%</td>
</tr>
<tr>
<td>Lovastatin</td>
<td>Mevacor</td>
<td>4,000</td>
<td>3,000</td>
<td>-23.7%</td>
</tr>
<tr>
<td>Pravastatin⁵</td>
<td>Pravachol</td>
<td>743,000</td>
<td>162,000</td>
<td>-78.2%</td>
</tr>
<tr>
<td>Pravastatin⁴,⁵</td>
<td>Generic</td>
<td>NA</td>
<td>611,000</td>
<td></td>
</tr>
<tr>
<td>Rosuvastatin</td>
<td>Crestor</td>
<td>849,000</td>
<td>1,127,000</td>
<td>+32.7%</td>
</tr>
<tr>
<td>Simvastatin⁴,⁶</td>
<td>Zocor</td>
<td>2,117,000</td>
<td>680,000</td>
<td>-67.9%</td>
</tr>
<tr>
<td>Simvastatin⁴,⁶</td>
<td>Generic</td>
<td>NA</td>
<td>1,982,000</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td>12,657,000</td>
<td>13,147,000</td>
<td>+3.9%</td>
</tr>
</tbody>
</table>

Source: Information derived by Consumer Reports Best Buy Drugs from data provided by Wolters Kluwer Health, Pharmaceutical Audit Suite.

1. Average is calculated over many months because prescriptions fluctuate from month to month. Numbers are also rounded.
2. Change is calculated base on average monthly prescriptions from first period to second period.
4. This version is the generic.
5. Generic pravastatin entered the market in May 2006.
Prescriptions for Vytorin continue to surge, as they have since the drug was first marketed in the summer of 2004. Vytorin continues to be heavily promoted in ads to doctors and consumers. Crestor also experienced healthy growth of about 33% between the two periods.

The market share of these three brand-name drugs – Crestor, Lipitor, and Vytorin – is the critical component in the evolving competition among statin drugs, and the crux of the issue surrounding cost savings in the category. If the market share of these three – currently around 60% – is sustained or grows in coming years, payers and consumers will see little savings overall. If the market share of the three declines, with a shift to the three less expensive generics, savings will be realized.

In a positive sign for generic uptake in the statin market, lovastatin prescriptions ticked up almost 14%. That’s on top of a 15% rise from 2004 to 2005. The average number of prescriptions for lovastatin has risen from 725,200 per month in early 2005 to 1.2 million per month in the last six months of 2006. This rise is especially significant since lovastatin is intended for people who need moderate cholesterol reduction, and it is no longer promoted to doctors or consumers. Its’ gain may signal a heightened awareness among doctors of the utility of this low-cost medicine for the millions of people who need modest LDL reduction.

Findings – Statin Price and Cost Trends

Prices rose modestly for all but one of the statins over the 15-month period examined. (See Table 2 on the next page.) All the statins except one were within the range of the general inflation rate during the period (2.5% between December 2005 and December 2006) and the medical products inflation rate during the period (3.6% between December 2005 and December 2006).

Statin prices were restrained by increasing competition among the seven drugs, and, in the latter part of 2006, by the market entry of pravastatin and simvastatin. In addition, large employers, pharmacy benefit managers, and government payers have put considerable pressure on pharmaceutical manufacturers and pharmacies to restrain price

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8 Data from 2005 released in a January 2006 study, available at www.CRBestBuyDrugs.org/PDFs/StatinAnalysis.pdf.
9 Lovastatin is intended only for people who need less than a 30% or so reduction in their LDL and have no or only one risk factor for heart disease, such as smoking, diabetes, or obesity.
Table 2. Statin Price Trend – October 2005 to December 2006

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Atorvastatin</td>
<td>Lipitor</td>
<td>$97</td>
<td>$98</td>
<td>+1.4%</td>
<td>$75-$130</td>
</tr>
<tr>
<td>Ezetimibe/Simvastatin</td>
<td>Vytorin</td>
<td>$87</td>
<td>$90</td>
<td>+3.3%</td>
<td>$80-$99</td>
</tr>
<tr>
<td>Fluvastatin</td>
<td>Lescol</td>
<td>$66</td>
<td>$67</td>
<td>+1.7%</td>
<td>$58-$86</td>
</tr>
<tr>
<td>Fluvastatin</td>
<td>Lescol XL</td>
<td>$82</td>
<td>$84</td>
<td>+2.1%</td>
<td>$75-$107</td>
</tr>
<tr>
<td>Lovastatin</td>
<td>Altoprev</td>
<td>$97</td>
<td>$102</td>
<td>+4.9%</td>
<td>$84-$117</td>
</tr>
<tr>
<td>Lovastatin</td>
<td>Mevacor</td>
<td>$98</td>
<td>$99</td>
<td>+0.8%</td>
<td>$37-$130</td>
</tr>
<tr>
<td>Lovastatin</td>
<td>Generic</td>
<td>$53</td>
<td>$51</td>
<td>-2.9%</td>
<td>$10-$46</td>
</tr>
<tr>
<td>Pravastatin</td>
<td>Pravachol</td>
<td>$127</td>
<td>$136</td>
<td>+6.6%</td>
<td>$88-$164</td>
</tr>
<tr>
<td>Pravastatin</td>
<td>Generic</td>
<td>NA</td>
<td>$90</td>
<td>NA</td>
<td>$58-$120</td>
</tr>
<tr>
<td>Rosuvastatin</td>
<td>Crestor</td>
<td>$89</td>
<td>$90</td>
<td>+1.4%</td>
<td>$81-$100</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>Zocor</td>
<td>$141</td>
<td>$144</td>
<td>+2.0%</td>
<td>$58-$155</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>Generic</td>
<td>NA</td>
<td>$109</td>
<td>NA</td>
<td>$38-$130</td>
</tr>
</tbody>
</table>

Source: Information derived by *Consumer Reports Best Buy Drugs* from data provided by Wolters Kluwer Health, Pharmaceutical Audit Suite, except where noted.

1. Table presents prices for all doses combined and averaged. Some drug companies charge roughly the same for the different doses of statins they offer while others price their lower doses at much less than higher doses.
2. Average of six months is calculated because prices may fluctuate month to month.
3. Monthly costs from online pharmacies were obtained by Consumers Union and do not come from Wolters Kluwer Health, Pharmaceutical Audit Suite. They are for all doses, and are ranges based on prices for both 30-day and 90-day prescriptions from four large online pharmacies. Data was obtained in late January 2007. Some costs range widely if a company charges less for lower doses and much for higher doses.
4. Higher doses are more expensive.
5. A sizable portion of lovastatin prescriptions are for the 40mg dose, which is more expensive. The 10mg and 20mg doses cost between $10 and $30 for a month’s supply.
6. Online prices for pravastatin and simvastatin were in transition in January 2007. Some online pharmacies had already begun offering these new generics at low prices, reflecting generic competition in the marketplace. Others had not.

hikes on many top-selling drugs over the past two years. Both drug makers and pharmacies have been motivated to comply by both public pressure and the launch of the new Medicare drug benefit. (The prices we present are for cash-paying customers, but those prices are affected by forces in the entire pharmaceutical marketplace.)

Altoprev, a long-acting “branded generic” form of the generic drugLovastatin, had the steepest cost increase for the second year in a row. The cost for a month’s supply of Altoprev has risen from just below $80 in late 2004 to more than $100 by December.
2006. That may account in large part for the continued drop-off in prescriptions for the drug, which is not widely prescribed.

Notably, the price for generic lovastatin continued to decline for the second year in a row. The many generic makers of this drug compete vigorously and payers continue to bargain down the cost. As presented in Table 2, the cost for a month’s supply of lovastatin obtained from online pharmacies can be as low as $10. This is generally for the 10mg version, but at some pharmacies the 20mg version is also priced at $10 to $20.11

Price competition and pressure from payers on statin prices is likely to intensify in 2007. Wal-Mart and Target in the late fall of 2006 added pravastatin to their list of $4-a-month drugs. This puts pressure on pharmacy chains to lower the price of pravastatin. It will also embolden pharmacy benefit managers and Medicare Part D plans to push for price concessions from manufacturers and distributors. Some observers are projecting that the monthly price for pravastatin may settle at between $10 and $20 at most pharmacies, including the negotiated transaction cost.

The price of simvastatin in 2007, and beyond, is less clear. It will likely remain more expensive than pravastatin for most of 2007 – between $20 and $40 for a month’s supply of the 20mg and 40mg doses. However, payers, PBMs, and especially Part D plans, may focus tightly on the price for this drug given its importance in the statin marketplace and the potential savings it can generate. If Wal-Mart, Sam’s Club, Target and other large discount retail stores add simvastatin to their list of inexpensive generics, price pressure on the drug at pharmacies will be enhanced.

Conclusion and Discussion

The market for statins in the U.S. is currently in transition as: (a) doctors choose from among seven competing drugs, including two new generics and the first potent generic statin; (b) consumers become increasingly aware of statins through routine cholesterol screening, discussions with their doctors, and direct-to-consumer drug ads; and (c) payers pressure drug companies and pharmacies to restrain statin prices or grant discounts and rebates.

Our prescription trend data reveal that, as anticipated, doctors, PBMs, insurers and pharmacies shifted prescriptions aggressively from two brand drugs that lost patent protection in 2006 – Pravachol and Zocor – to the new generic versions of both. However, as of late 2006, more expensive brand-name statins retained significant market share (71%).

We find that companies and pharmacies 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 most widely prescribed drugs.

11 Like all statins, lovastatin tablets can be split in half. This can decrease the price to the patient even more.
Most observers concur that while price concessions are important, the largest savings opportunity in the statin marketplace would occur from increased use of the available generic statins. In January 2006, we estimated that an aggressive switch to the use of generic statins in 2007 could cut overall statin spending for and by the 43 million Medicare beneficiaries roughly in half.\textsuperscript{12} An update of that analysis is underway and will be released soon.

The new Medicare drug benefit is providing improved access to prescription drugs, including statins, for millions of Medicare beneficiaries. At the same time, however, it adds a significant fiscal burden to the Medicare program and the federal government. Despite recent favorable forecasts of less-than-projected spending on the Part D program over the next decade, it is crucial that policymakers take maximum advantage of savings opportunities such as those now presented by the availability of generic statins.

\textit{This analysis was written by Steven Findlay with research assistance from Delani Gunawardena, Keith Newsome-Stewart, and Ginger Skinner. Thanks to Gail Shearer, Chris Hendel, and Susan Herold for comments on early drafts. For further information, or to comment, call or email Steven Findlay at 202-238-9248 or findst@consumer.org.}

\textsuperscript{12} Study available at \url{www.CRBestBuyDrugs.org/PDFs/StatinAnalysis.pdf}.