Published in final edited form as:

N Engl J Med. 2012 January 19; 366(3): 201–204. doi:10.1056/NEJMp1113112.

Generic Atorvastatin and Health Care Costs

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Lipitor[®] was the top selling prescription medication in the United States in 2010 with over \$7B in total revenue. The overall lipid lowering prescription market continues to grow and was ranked the top drug class in prescription volume in 2010, with statins dominating the market. ¹Lipitor's[®] patent expired in June 2011, and the first generic product of this high-potency statin is expected on the market as of November 30, 2011.^{1,2}

The US healthcare system is financially constrained and searching for ways to safely and effectively cut costs. Since generics are less costly than brand name formulations, and are often considered bioequivalent, promotion of generic substitution by health plans is a popular strategy to blunt the growth in prescription drug spending. Over the next few years, as several blockbuster drugs, including Lipitor[®], lose their patent, generic products will be increasingly available.

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Author access to data: Dr. Jackevicius had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

To provide perspective on the possible economic impact of generic Lipitor® (atorvastatin), we examined past trends in statin use to project potential future cost savings using the National Prescription Audit® from IMS Health between 2002 and 2009 for the US market. A similar scenario of generic entry of simvastatin for Zocor® in 2006 provided a historical example to guide our projections, including information on timing of generic product use, changes in the average price of generic and brand products, and the extent of switching to other statins within the class. We also considered the impact that the aging of the population would have on increasing the demand for statins in our projections. We expect that our estimates of cost savings with generic Lipitor® are conservative compared with the historical Zocor® patterns we examined. At generic entry, Zocor® had immense competition from the high-potency statin Lipitor®, while at the present time of generic entry of Lipitor®, competition is limited. Even the newest statin, Crestor®, has not shown superiority over Lipitor® and is unlikely to command a large share of the statin market in the US.³

We found that in the United States, Lipitor®, Crestor®, and generic simvastatin accounted for 77% of the statin market in 2009. Lipitor® market share dropped from 44% in 2006 to 26% in 2009, while simvastatin dominated the statin market in 2009 with a market share of 41%, likely due to its generic availability. (Figure)

The projected market share of Lipitor® and simvastatin at time of generic Lipitor® entry is expected to be 21% and 51%, respectively. According to our assumptions, generic Lipitor® will dominate the statin market as a result of switching from simvastatin, as well as switching from Crestor®, with an estimated market share of 44% three years after market entry. (Figure)

The historical trends show that the price of generic Zocor® one month after market entry was 84% of the average brand price in the quarter before first generic entry, 81% after 6 months, 40% after 12 months, and 39% after 36 months. Using these trends, the price ratio at time of generic atorvastatin entry is projected to be 0.82, 0.49 after the 6 month exclusivity period of the first generic product. The overall cost savings from generic Lipitor® availability is projected to reach \$4.7 billion annually by 2014, representing 24% of the total statin expenditures in 2014. (Table) When factoring in the aging of the population, the projected cost savings increase by \$10 million up to \$30 million annually between 2012 and 2014.

Our estimates project what would happen with a timely response to generic Lipitor®. However, delays in realizing these savings have already started to accrue. A mutual agreement between Pfizer and the first generic company Ranbaxy that has received limited attention has already deferred introduction of the first generic version of Lipitor® on the US market by five months. This agreement has now cost Americans \$324B in estimated savings on prescription drug spending. And now, an FDA investigation into quality standards at two Ranbaxy manufacturing plants has further setback approval of their generic version of Lipitor®.⁴ Some physicians or health plans may reconsider switching to the Ranbaxy generic product in response, further delaying the expected cost savings. However, given this intense scrutiny of Ranbaxy's facilities by the FDA, once the product is given FDA approval, there should be reassurance that quality standards have been achieved. Furthermore, in order to be considered interchangeable with Lipitor®, all generic products must have met pre-specified bioequivalence standards in order for the FDA to grant a bioequivalent rating for the product. Regardless of whether Ranbaxy's atorvastatin is available for launch on November 30, 2011, Pfizer has an agreement to provide Watson Pharmaceuticals with Lipitor® to sell without the brand label on that date in return for a share of sales.⁴

In response to the generic product threat, Pfizer has employed aggressive business tactics to retain continued Lipitor® revenue at unclear cost to patients and health plans. Pfizer has created strategic agreements with several pharmacy benefits management (PBM) and insurance companies to provide Lipitor® at less than the cost of the first generic atorvastatin with a generic-level co-pay for patients in exchange for a monopoly on atorvastatin prescriptions dispensed. While it is clear that Pfizer benefits from this, whether these low-cost Lipitor® agreements provide savings to the employers who fund the healthcare plans or to the PBMs is uncertain. Of concern is whether these agreements will discourage the number of competing generic manufacturers of atorvastatin.

In December 2010, Pfizer launched the Lipitor® for You Program with a \$4 co-pay card as another strategy to retain its market share, attract new users and limit the rate of revenue loss after patent expiry. Although the co-pay card appears to provide a cost saving solution for patients, the public, through the insurance company, is still burdened with the remaining higher cost of the brand name prescription product. The \$4 co-pay card is set to expire in December 2012 but in the meantime has likely helped Pfizer temporarily reduce its loss in Lipitor® sales. Finally, it is expected that Pfizer is planning to propose an over-the-counter version of Lipitor® to the FDA as another outlet for continued Lipitor® sales. However, given that Mevacor was denied similar status due to concern over consumers' ability to determine their own need for a statin, this strategy holds less promise.

In order to capitalize on this opportunity for cost savings with patent expiry, there must be a rapid, concerted effort by many players in the healthcare system. Although generic substitution laws and tiered formularies have attempted to promote use of generic products for years, preference for brand name medications persists. For statins alone, examination of actual prescribing patterns in primary care practice reveal that brand name product preference may result in an excess of \$5.8 billion in expenditures annually.⁵ If Pfizer's recent agreements that create a temporary monopoly for Lipitor® truly provide a brand name drug at a generic price with savings realized by the patient, PBM, insurance company and employer, the only short-term losers appear to be the competing generic companies. However, without the possibility of gaining some of the atorvastatin marketshare, generic companies may forgo competition, preventing the typically sharp decline in the price of generic atorvastatin in the long-term, resulting in a lost opportunity for cost savings in prescription drug spending for the entire health care system.

Acknowledgments

We gratefully acknowledge IMS Health-US for providing the data required for the analyses from the National Prescription Audit™. The statements, findings, conclusions, views, and opinions contained and expressed in this article are based in part on data obtained under license from the IMS Health National Prescription Audit™ (2002-2009). All Rights Reserved. The statements, findings, conclusions, views, and opinions contained and expressed herein are not necessarily those of IMS Health Incorporated or any of its affiliated or subsidiary entities.

Funding sources: This study was funded in part by the College of Pharmacy of Western University of Health Sciences, Pomona, California. Western University was not involved in the design and conduct of the study; collection, management, analysis or interpretation of the data; and preparation, review or approval of the manuscript. Dr. Krumholz is supported by grant U01-HL105270 (Center for Cardiovascular Outcomes Research at Yale University) from the National Heart, Lung, and Blood Institute. Dr. Ross is currently supported by the National Institute on Aging (K08 AG032886) and by the American Federation of Aging Research through the Paul B. Beeson Career Development Award Program. The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs. Neither the Department of Veterans Affairs nor the Hartford Foundation had any role in the design or conduct of the study; collection, management, analysis or interpretation of the data; preparation, review or approval of the manuscript.

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Figure. U.S. Statin Market Share Pre- and Post- Generic Atorvastatin Entry
 GE=generic entry. **Source: IMS Health National Prescription Audit™ 2002-2009**

Table

Projected Cost Savings after Atorvastatin Generic Entry

	2012	2013	2014
Cost Savings	\$3,740,645,782	\$4,345,146,492	\$4,721,111,909
Total Statin Expenditure without Generic Entry	\$18,037,266,557	\$18,962,374,802	\$19,887,483,046
% Cost Savings	21%	23%	24%

Source: IMS Health National