

- Rx Focus - Crestor®
- Industry Report
- State & Federal Updates
- New Drug Approvals



Rx Focus

Crestor® (Rosuvastatin)

On July 9th a US advisory panel unanimously supported the approval of AstraZeneca's blockbuster cholesterol lowering drug Crestor. The Food and Drug Administration panel voted 9-0 to recommend that the agency clear doses from five to 40 milligrams. The FDA generally follows the advice of its panels.

Crestor's peak sales could hit \$3 billion worldwide, analysts have said. The drug is part of a class known as statins, or pills taken by millions to lower cholesterol, a major risk factor for heart disease.

AstraZeneca said studies showed Crestor worked better than currently marketed statins, with similar safety. Panel members said Crestor would be useful for patients whose cholesterol is not adequately controlled using current therapies. Other statins include Pfizer Inc.'s Lipitor, Merck & Co Inc's Zocor, and Bristol-Myers Squibb Co.'s Pravachol. Lipitor is the top-selling drug in the world, with sales of about \$8 billion in 2002. AstraZeneca has said Crestor could capture up to 20 percent of the huge worldwide market for statins, which now stands at about \$19 billion per year.

One study comparing Crestor and Lipitor showed various doses of Crestor reduced LDL, the so-called bad cholesterol, by 46 to 55 percent, while various Lipitor doses cut LDL by 37 to 51 percent. The FDA is expected to decide by August 12 whether to approve Crestor, company officials said. FDA staff who reviewed the drug had expressed concerns about possible kidney side effects with Crestor's 40 milligram dose because some patients' urine had elevated protein levels.

AstraZeneca said the elevations were reversible and had not been shown to impair kidney function at the 40 milligram dose. Still, the advisory panel agreed that doctors should watch for kidney toxicity in patients taking the highest dose.

Crestor already is approved in 24 countries, including Canada and parts of Europe, but U.S. approval was delayed after regulators last year asked for more information.



Industry Report

Direct to Consumer Advertising (DTCA)

Direct-to-consumer advertising (DTCA) of pharmaceuticals has come a long way since its introduction in 1985. Originally, the Food and Drug Administration (FDA) permitted DTCA under the same basic standards that existed for product advertising to physicians. In 1997, additional DTCA guidelines were issued requiring the truthful description of a drug's indication, a major statement about side effects and contraindications, and instructions on how consumers can obtain detailed information about the advertised drug.

DTCA accounts for approximately 16% of total promotional spending by pharmaceutical companies. Spending on DTCA has increased from \$600 million in 1996 to approximately \$2.5 billion in 2000. Put into perspective, the amount spent on DTCA is beginning to rival other mass media product spending. For instance, the pharmaceutical company, Merck, spent an equivalent amount marketing its arthritis drug, Vioxx®, as did General Motors on the Saturn car line and Dell Computer Company on its top brands of computers. Promotional spending on Vioxx® was higher than individual marketing costs for Pepsi®, Nike®, Campbell's Soups® and Budweiser® products¹.

DTCA increases consumer awareness of available pharmaceutical medications. However, many of the ads appeal to emotions and encourage consumers to view the product as a quick, easy fix to their ailment. Patients begin to ask for medications by name and prescribers may yield to pressure in order to attract and retain patients. Increases in the sales of the 50 drugs most heavily advertised to consumers in 2000 were responsible for almost half of the \$20.8 billion increase in retail spending on prescription drugs from 1999 to 2000. The number of prescriptions for the 50 most heavily advertised drugs rose 24.6% from 1999 to 2000, compared to an increase of 4.3% for all other drugs combined.

Plan sponsors can assist by educating their members on DTCA medications. These advertised medications are not necessarily the best or most cost effective options and may not provide all the benefits as promoted.

References:

1. National Institute for Health Care Management. Prescription Drugs and Mass Media Advertising, 2000. Available from URL: <http://www.nihcm.org>



State & Federal Updates

The U.S. Senate and House of Representatives approved landmark Medicare drug bills on June 27th that would give older Americans long-awaited help in paying for their prescription medicines.

The \$400 billion, 10-year Medicare plan would, for the first time, give all seniors federal subsidies to buy prescription drugs, relying primarily on private companies to deliver the benefit. It also would create a new Medicare-managed care option preferred provider organizations which supporters hope would give seniors more choice while saving the government money.

The House and the Senate bills have different deductibles and formulas for sharing drug costs with the elderly. The House measure allows competitive bidding by companies for the right to offer drug insurance to Medicare beneficiaries. The Senate bill requires Medicare to offer the benefit if two or more insurers don't participate in a given region. Under the Senate bill, seniors would pay a \$275 deductible and an average \$35 monthly premium. The government would split costs 50-50 with patients for expenses up to \$4,500. Then coverage would end until out-of-pocket costs exceeded \$3,700. The government then would pay 90 percent of prescription expenses.

Under the House legislation, patients would pay a \$250 annual deductible and a monthly premium of about \$35. Medicare would pay 80 percent of an individual's prescription drug costs up to \$2,000, and patients would pick up the remaining 20 percent. For patients whose annual drug bills exceed \$2,000, Medicare would step in and pay for drugs after patients spent \$3,500 out of pocket each year.



New Drug Approvals

Xolair[®] Approved 6/20/03

Approved Indications: Treatment of allergy related asthma
Average Wholesale Price: \$541.25 per unit
Special Notes: First biological injectable for the treatment of allergic asthma.

Reyataz[™] Approved 6/20/03

Approved Indications: Treatment of HIV infection
Average Wholesale Price: \$13.80 per unit
Other Drugs in Class: Norvir , Viracept

Striant[™] Approved 6/20/03

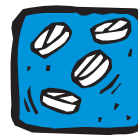
Approved Indications: Testosterone replacement in men
Other Drugs in class: Androgel, Testoderm, Depo Testosterone
Average Wholesale Price: \$3.17 per unit
Special Notes: Striant will be excluded from all plans that don't cover other testosterone products.



New Generic Approvals

Mirtazapine: (6/19/03)

Brand name equivalent: Remeron[®] Tablets
Manufacturer: Watson Pharmaceuticals



New Over-the-Counter Approvals

On June 23rd 2003 the Food and Drug Administration (FDA) approved the over the counter (OTC) sale of Prilosec for short-term treatment of heartburn. Prilosec[®] will also continue its prescription status for treatment of other conditions that warrant close monitoring by a health care provider. Proctor & Gamble and Astra Zeneca will have market exclusivity for the next 3 years for OTC Prilosec.

Prilosec[®] had been the top prescribes medication from 1996 to 2000, with sales topping 3 billion dollars a year in the US alone. As a class, the Proton Pump Inhibitors (PPI) which include other top selling drugs Prevacid[®], Aciphex[®], Nexium[®] are one of the most expensive prescription medications currently being utilized through pharmacy benefits. With an average cost of \$4.00 per day, OTC Prilosec[®] is welcome news for the insurance industry and the consumers alike. Early estimates suggest the cost of OTC Prilosec[®] to be around a \$1.00 per dose, resulting in substantial savings over the long run. A September 2003 released date is predicted.



675 Foxon Road, Suite 204
East Haven CT 06513
Phone: (800) 936-1193
Fax: (203) 468-8416