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U.S. Cholesterol-Lowering Drugs 2005: Rx Market Analysis and Switch Forecasts

An in-depth analysis of the prescription cholesterol-lowering drug market and the potential for Rx-to-OTC switches in this class in the United States



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Kline & Company is pleased to present a new market analysis from its Healthcare Practice. [U.S. Cholesterol-Lowering Drugs 2005: Rx Market Analysis and Switch Forecasts](#) is designed to explore this dynamic and profitable market. The study provides the following:

- A comprehensive analysis of the prescription cholesterol-lowering drug market
- A review of major healthcare trends, including cost containment of prescription drugs, the FDA's fostering of more Rx-to-OTC switches, and the paradigm shift to make drugs used to treat chronic, asymptomatic conditions available as OTCs
- Details on currently available OTCs and consumer products used to help manage cholesterol levels
- An assessment of the likelihood of Rx-to-OTC switches in the product class, regulatory issues, sales potential of OTCs, the impact on related OTC markets such as home diagnostics, and likely retail scenarios that such products will be sold in
- Healthcare professionals' viewpoints on Rx-to-OTC switches of statins
- An interactive FutureView forecasting tool that subscribers can modify to help forecast sales and opportunities in this category





1. Introduction

2. Executive Summary

- Likely Rx and potential OTC market scenarios for cholesterol-lowering drugs
- Summary of regulatory issues surrounding Rx-to-OTC switches of statins
- Likelihood of switch
- Forecasts of likely OTC brands, pricing, retail availability, corporate strategies, effects on Rx market

3. Background

- Incidence and prevalence now and in the future
- New guidelines for diagnosis (HDL and LDL levels)
- Summary of Heart Protection Study, National Cholesterol Education Program, and other recent studies
- Overview of currently available OTCs used to help manage cholesterol levels including medical foods, dietary supplements, functional spreads, and home diagnostics test kits

4. Rx Market Analysis

- Breakdown of the market by class
- Description of pipeline products
- Cost analysis of drugs
- Manufacturer analysis
- Safety and efficacy of statins

5. Profiles of Rx Drugs

This section provides analysis of the market and the following for each Rx drug listed in Table 1.

- Sales
- Market share

- DTC advertising expenditures
- Patent status
- Indications
- Dosages
- Future sales and market share projections

6. Healthcare Professionals' Perspectives

This section provides a summary of the findings from Kline's surveys of pharmacists and physicians regarding Rx-to-OTC switches.

- Switch likelihood
- Feasibility of OTC cholesterol reducers
- "Pharmacy care OTCs"
- Opinions about OTC statins and non-OTC statins
- Pricing for OTC cholesterol reducers
- Educational materials and programs for OTC cholesterol reducers
- Nutritional supplements to help manage cholesterol levels

7. Rx-to-OTC-Switch Forecast

- Regulatory issues and past FDA denials
- Impact of Rx-to-OTC switch in U.K. on U.S. decision
- Which brands are likely to switch (see Table 2)
- Likely timing of switches
- Likely indications, dosages, retail scenarios
- Role of healthcare professionals in switch sales
- Impacts on home diagnostic test kit sales
- Forecast sales of switch brands
- Forecast reactions of managed care organizations, such as changes in coverage in cholesterol class, changes in copayments, etc.

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Table 1. Rx DRUGS PROFILED IN THE STUDY

Drug	Company
Advicor	Kos
Atromid-S	Wyeth
Colestid	Pfizer
Crestor	AstraZeneca
Lescol	Novartis
Lipitor	Pfizer
Lopid	Pfizer
Mevacor	Merck
Niaspan	Kos
Pravachol	Bristol-Myers Squibb
Questran/Questran Light	Undisclosed
Tricor	Abbott Laboratories
Vytorin	Merck/Schering-Plough
WelChol	Sankyo
Zetia	Merck/Schering-Plough
Zocor	Merck

Table 2. CANDIDATES FOR Rx-TO-OTC SWITCH ANALYZED IN THE STUDY

Drug	Company
Mevacor	Merck
Pravachol	Bristol-Myers Squibb
Lescol	Novartis
Lipitor	Pfizer
Zocor	Merck

Market Overview

The U.S. market for cholesterol-lowering drugs is highly dynamic and is experiencing major transformations. This huge market is growing rapidly and consists of enormously successful blockbuster drugs like Pfizer's Lipitor. Newer drugs have recently been launched to compete with Lipitor, including AstraZeneca's Crestor, as well as Zetia and Vytorin, both marketed by Merck and Schering-Plough. At the same time, the patent for Mevacor (Merck) has already expired, and other drugs will lose patent protection over the next two years, including Pravachol (Bristol-Myers Squibb), Lipitor (Pfizer), and Zocor (Merck).

Despite the multitude of pharmaceutical agents available for treating high cholesterol levels, the prevalence of this condition continues to rise in the United States each year. As the population ages and unhealthy diets and sedentary lifestyles persist, the condition continues to affect more Americans.

It is estimated that 200 million Americans are in need of treatment for high cholesterol, but only one in eight of these patients are receiving care. There is a real need for Americans to reduce their cholesterol levels in order to avoid complications associated with this condition, including heart attack, stroke, and coronary heart disease (CHD). In 2004, the total market for prescription cholesterol drugs is \$15.7 billion, as shown in Figure 1.

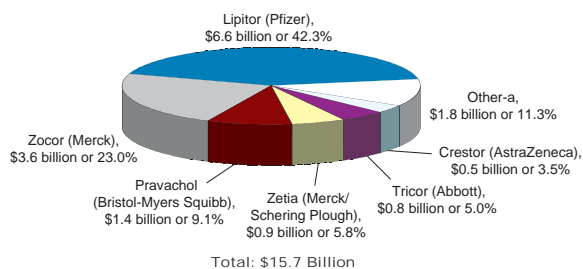
In July 2004, the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) approved Merck's Zocor Heart Pro 10 mg simvastatin for OTC sale through pharmacy outlets to patients with low to moderate risk factors for elevated cholesterol or coronary heart disease. Through collaborative care such as interaction with a pharmacist, patients will be assessed for risk factors and, if appropriate, this drug will be sold to them without a prescription.



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Figure 1
U.S. PRESCRIPTION CHOLESTEROL MARKET, 2004



a- Includes Vytorin (Merck/Schering Plough) and Lescol (Novartis) and other brands and generics.

The United Kingdom is the first country to allow the OTC sale of a cholesterol-lowering agent, and other countries, including the United States, are watching closely.

There is also a need to reduce prescription drug expenditures in the United States, and one of the ways the FDA intends to accomplish this is to shift more costs to consumers by increasing the number of Rx-to-OTC switches. The FDA has publicly stated that it would like to increase the number of Rx-to-OTC switches by as much as 50%, that it will consider applications for drugs used to treat chronic conditions, and that it will consider foreign clinical trial data in support of switches in the United States.

The FDA has also stated that the agency would reconsider switches for drugs it previously denied. The FDA was scheduled to review Mevacor and Pravachol switch applications in May 2005. The agency denied switch applications for both of these drugs in 2000 based on safety concerns, so the revised switch applications needed to address these concerns. They should have also detailed some creative ways to make these products available without a prescription and still be safely used by consumers.

In July 2004, new guidelines for diagnosing high cholesterol were issued by the National Cholesterol Education Program, stating that those at high risk of CHD should attempt to bring their LDL (or "bad" cholesterol) numbers below 70 mg/dL. In the past, patients were told to reduce LDL levels to 100 mg/dL or less.

Objectives

U.S. Cholesterol-Lowering Drugs 2005: Rx Market Analysis and Switch Forecasts provides subscribers with a comprehensive analysis of the prescription and OTC markets for cholesterol-lowering drugs and the likelihood that cholesterol-lowering drugs will make the Rx-to-OTC switch in the United States.

The study forecasts likely OTC and prescription sales over the next five years, discusses the regulatory hurdles to be overcome in order to make switches a reality, and examines the likely retail scenarios that such OTCs will be sold in.

This report was compiled via a combination of primary and secondary market research, with emphasis placed on primary interviews. This research considers not only the perspective from the industry side but that of other major stakeholders, including regulatory agencies, third-party payers, consumer advocacy groups, and healthcare professionals. This approach has yielded accurate and actionable forecasts for future switches that incorporate the perspectives of most of the relevant parties.

Methodology

The forecasts, data, and insights provided in this report are based on both primary and secondary sources, building on Kline & Company's extensive databases of Rx and OTC pharmaceutical information.

In order to develop their forecasts, Kline's seasoned consultants conducted in-depth interviews with pharmaceutical industry executives, FDA staff, academic researchers, opinion leaders in cholesterol, industry associations, consumer advocacy groups, MCOs/PBMs, and retailers.

In addition to these interviews, Kline's Call Center conducted surveys of pharmacists and physicians, including cardiologists and internists/general practitioners, to obtain the perspective of these important groups of healthcare professionals.



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Details on the groups that were interviewed for this study are provided in Figure 2.

Forecasts in this report were generated with Kline's new FutureView analytical forecasting tool. With the enhanced forecasts, subscribers can see how adjustments in the assumptions behind the forecasts can effect different outcomes.

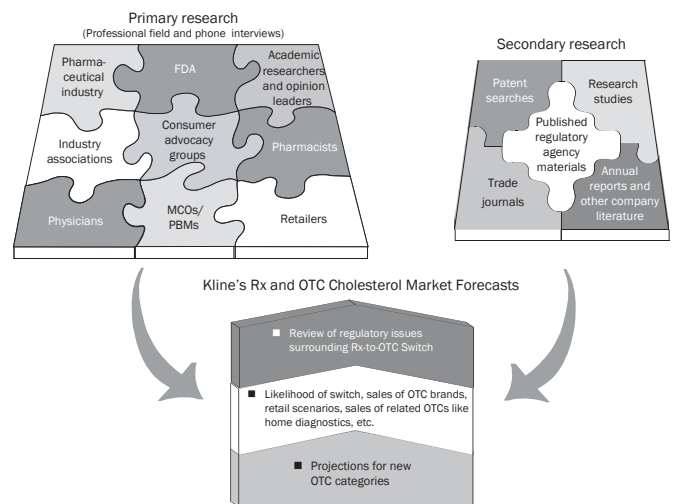
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- Access to Kline's new **FutureView analytical forecasting tool**, which can be used to forecast prescription and OTC sales. The model contains variables that subscribers can adjust to develop their own forecasts.

Details regarding subscription options and rates are described in the attached subscription agreement. To subscribe now, please complete the subscription agreement and forward it to our offices. For more details on the study program, please contact us at any of our locations listed on the back cover.

Figure 2
METHODOLOGY



Credentials

Kline & Company is an international business consulting firm offering a broad range of services to the pharmaceutical and healthcare industries.

The firm helps clients solve practical issues in marketing, strategy development and implementation, franchise management, licensing/acquisition analysis, customer satisfaction analysis, consumer attitudes and perception research, and competitive intelligence.

Kline provides its clients with facts, forecasts, and recommended solutions, based solidly in the realities of the market and modern strategic principles.

Since its inception in 1959, Kline has earned a reputation for delivering high-quality analyses and technology assessments. We complete approximately 200 custom consulting assignments and complete more than 25 multiclient research reports each year.

As part of our syndicated research services, Kline has a long history of providing comprehensive insightful reports for the OTC industry.

Kline has examined the OTC market for nearly 40 years through its *Nonprescription Drugs USA* annual continuing study. Other previously published studies related to the pharmaceutical industry include:

- Rx-to-OTC Switch: The Next Wave (2002)
- Nonprescription Drugs Canada (biennial study)
- Competitor Cost Structures 2001: Nonprescription Drugs
- Functional Foods, A Competitive Landscape (2000)
- History and Impact of the Rx-to-OTC Switch (1996)
- More Power for the Rx-to-OTC Switch (1995)
- Retailer Perceptions of OTC Drug Marketers 2004
- OTCs in Managed Care: Taking the Pulse of MCOs and PBMs, 2004
- International Rx-to-OTC Switch Forecasts

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