CONTEMPORARY SUBJECT

Managed Care Market Perspectives on the Over-the-Counter Availability of Statins

MEGAN K. RICHARDS, STEVEN BLUMENFIELD, and RONALD A. LYON, MS, RPh

ABSTRACT

OBJECTIVE: In April, May, and June 2003, we conducted market research with decision makers from 3 payer segments to determine their perspectives on the potential introduction of statins to the U.S. over-the-counter (OTC) market.

METHODS: We selected a convenience sample of survey participants based upon prominence in the market, membership size, and by willingness to participate in our study. The 12 participating managed care organizations (MCOs) cover approximately 100 million lives. The 4 pharmacy benefit managers (PBMs) cover approximately 200 million lives. The 3 large employers (one employer withheld quantitative results) provide medical coverage to nearly 1.4 million employees, both actives and retirees. Each survey participant received a verbal description of an OTC statin and a proposed patient self-management system. We asked each participant a series of questions to obtain opinions on a number of issues related to the potential introduction of an OTC statin.

RESULTS: Our research findings can be summarized in the following key conclusions: (1) MCO representatives generally view OTC statins as a low-risk and beneficial addition to drug therapy options; (2) payer policies will continue to support access to prescription statins with no change in policy following introduction of an OTC option; (3) several of the MCOs and 75% of the PBMs anticipate a sharp, short-term increase in plan costs as a consequence of OTC statin availability; (4) survey participants believe that consumer or member reaction will be mixed and that consumer advertising and physician education will be important; (5) MCOs and PBMs are eager for involvement but cautious about partnerships with pharmaceutical companies; and (6) the details of any OTC statin offering will lay the foundation for its success.

CONCLUSIONS: Based upon interviews conducted from April through June 2003, key decision makers from 4 PBMs, 12 MCOs, and 3 large employers generally considered the introduction of an OTC statin as a low risk and a beneficial addition to drug therapy. Most believed that increased awareness would result in an initial increase in plan costs, but long-term savings would accrue through improved care and availability of lower-cost OTC options for low-to-moderate-risk patients. The key concern is how to help patients gain enough knowledge and comfort to manage their own cholesterol therapy safely and successfully.

KEYWORDS: Statins, Cholesterol, Over-the-counter, Survey, Market research

J Manag Care Pharm. 2004:10(6):543-50

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Heart disease is one of the most important public health issues we face in the United States. It accounts for approximately 38% of all-cause mortality and is the number one cause of death.[1] Because of its prevalence, heart disease accounts for an estimated 24% of total U.S. health expenditures[2] and a total economic burden of $368 billion for 2004.[3] Continued aging of the population will likely increase the number of deaths and costs associated with heart disease.

Extensive efforts continue to address the heart disease epidemic. The Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults estimates that 36 million people would benefit from cholesterol-lowering drug therapy, and their most recent set of treatment guidelines (Adult Treatment Panel III, or ATP III) are well known within the medical community.[4] However, their report suggests that less than one half of patients who qualify for lipid-modifying drug therapy actually receive treatment. This is consistent with a review of claims from a database representing 70 health plans and 42 million lives that showed that, even with drug coverage, approximately one half of patients with high cholesterol do not receive appropriate drug therapy.[5] Despite this treatment gap, statins account for approximately 6.4% of all prescription drug sales in the United States.[6]

ATP III guidelines also added a strong focus on primary prevention as the best means to reduce the overall population burden of heart disease. Studies suggest an even greater treatment gap exists within the moderate risk primary prevention group. One study of claims data suggested that only 18% of patients who would qualify for drug therapy for primary prevention received treatment.[7]

The ATP III guidelines suggest that drug therapy begin with a statin, bile acid sequestrant, or nicotinic acid but identify the statins as the most effective drugs for lowering low-density lipoprotein (LDL) cholesterol concentrations. Five clinical trials, involving approximately 30,000 patients, documented a decrease in coronary heart disease and total mortality, myocardial infarctions, revascularization procedures, stroke, and peripheral vascular disease. These results occurred for men and women and for primary and secondary prevention, with a favorable safety record in the use of statins.

Over-the-counter (OTC) statins may provide an important public health benefit for persons at low to moderate risk of coronary heart disease. A switch from a prescription-only to OTC status may increase access and expand the use of certain treatments.[8] In 1992, a market research firm found that the introduction of prescription nicotine patches increased the number of medication-assisted quit attempts from approximately 2 million to 7 million per year. However, the number of quit attempts then decreased to approximately 2 to

3 million per year over the next 3 years. With the availability of OTC nicotine products in 1996, the number of attempts increased to approximately 6 million per year.

The United Kingdom approved an OTC version of simvastatin in a 10 mg strength in May 2004. Following this approval, Minhas reviewed the implications for the United Kingdom and compared them with the decision by the U.S. Food and Drug Administration (FDA) in 2000 not to approve OTC status for lovastatin and pravastatin.[9] A primary concern in the United States involved the ability of patients to self-treat without blood testing of lipid levels. In the United Kingdom, OTC product does not include recommendations for measurements of LDL cholesterol; rather, it focuses on risk related to demographics and other factors. In addition to a patient self-check list, the United Kingdom includes the use of a pharmacist to assist with patient selection and training. Minhas also described other FDA concerns related to the introduction of an OTC statin, including compliance, treatment to goal, dosage titration, and potential for adverse reactions.[9]

In addition to these concerns, the reaction of managed care to a potential switch is also a key issue. When loratadine (Claritin), a prescription nonsedating antihistamine, switched to OTC availability, many managed care organizations (MCOs) took proactive measures to limit the usage of all prescription nonsedating antihistamines.[10] This included stopping reimbursement and shifting to higher copayments.

Following the OTC introduction of omeprazole (Prilsoec OTC), a proton pump inhibitor used in the treatment of upper gastrointestinal disorders such as heartburn, ulcers, and gastroesophageal reflux disease (GERD), some MCOs discontinued coverage of prescription versions of omeprazole. In addition, some moved select proton pump inhibitors to a higher copayment level. If the managed care reaction would be the same in the event of OTC statins, this might reduce the number of people taking statins to lower their risk of heart disease. However, in a recent article, Harris et al. reported that coverage of OTC omeprazole resulted in an approximate 39% reduction in per-member-per-month costs for proton pump inhibitors despite an initial 17% increase in utilization.[11]

Because of specific interest in how managed care might react to an OTC statin, a pharmaceutical company engaged our services to assess the current opinions of payers on self-treatment and benefit coverage issues surrounding OTC statins. The introduction of OTC versions of loratadine and omeprazole has provided payers with the opportunity to assess the impact of these products on patient access, efficacy, and safety. Our research assessed opinions related to improved access to care, patient self-treatment, and the potential benefit of a proposed patient self-management system related to use of an OTC statin. In conjunction with these opinions, the research assessed the types and likelihood of policy changes related to introduction of an OTC statin that may affect the access of patients to appropriate prescription statin therapy. This information may be useful to MCOs for advance decision making to take maximum advantage of a potential OTC statin introduction.

Methods

For this report, we conducted market research with decision makers from 12 MCOs, which cover approximately 100 million lives; 4 pharmacy benefit managers (PBMs), which cover approximately 200 million lives; and 3 large private-sector employers, which provide medical and prescription drug coverage to nearly 1.4 million employees and retirees, to determine their perspectives on the potential introduction of OTC statins. One employer requested that its perspectives be excluded from the quantitative results but permitted inclusion of their qualitative results.

We conducted telephone interviews with participants during April, May, and June 2003. Participants were primarily chief medical or pharmacy officers. Most interview participants were or had been practicing medicine or pharmacy at some point in their career. Interviews involved 1 to 3 senior decision makers in each organization and lasted up to 45 minutes. For confidentiality reasons, research participants were not provided electronic or hard copies of the information discussed. However, we provided a verbal description of an OTC statin and a proposed patient self-management system. We reminded participants that the information discussed was confidential, that an OTC statin is not a currently available product, and that the OTC statin self-management system is in an early developmental stage.

All of the interviews began with a detailed overview of the concept of an OTC statin and the self-management system. Background on the most recent National Cholesterol Education Program guidelines (NCEP ATP III) and statistics regarding the number of people eligible for statin therapy, versus those treated, were shared with participants. In addition, we provided a high-level overview of an OTC statin, including target population, dosage safety profile, and label indications. The components of the OTC statin self-management system that were discussed include:

- Responsible communication targeting appropriate consumers
- Prepurchase consumer assistance program
- Package labeling
- Enhanced retail support
- Informative packaging and self-management materials
- Referral systems
  a. High-risk referral
  b. Cholesterol-testing referral
- Postpurchase program

The interview process asked participants for their opinions on a number of critical issues related to an OTC statin:

- Current practices for people in low-, moderate-, and high-risk categories
- Initial responses to the concept of OTC statin availability
- Potential changes to policies or coverage of prescription statins if an OTC becomes available

- Potential for appropriate OTC statin coverage and payer support
- Cost-savings potential related to OTC statin coverage
- Member/employee considerations
- Possible partnerships between the drug company and MCOs or PBMs
- Similarities between an OTC statin introduction and other OTC introductions.

The following pages contain key interview findings supported with question-by-question detail from research participants. The conclusion and key findings appear first, followed by quantitative support from interviews. Qualitative commentary, including quotes and comparator data, supports each quantitative illustration.

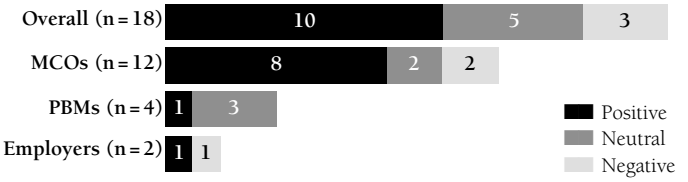
Results

Conclusion 1: Participants generally view OTC statins as a beneficial addition to therapy.

Ten out of 18 participants (56%) view an OTC statin as a positive addition to the market for people in the low-to-moderate risk group. Most also believe that an OTC option would increase consumer convenience and eliminate an access issue, both of which currently prevent many people from treating low-to-moderate risk cholesterol levels. There was clear agreement that more people will be on statins if an OTC option is available. Participants believed that both prescription and OTC utilization would grow because of increased consumer awareness. They also described a number of unknowns and raised questions about acquisition cost, retail price, compliance issues regarding an OTC drug, and an appreciation that a prescription statin will still be needed by many members.

Interview Question: "What is your initial response to the use of an OTC statin for people in the low-to-moderate risk group?"

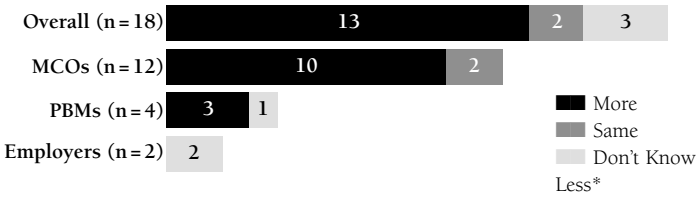
The Number of Positive Versus Negative Versus Neutral Initial Reactions



Positive Reactions	Negative Concerns	Neutral Reasons
• OTC statins may help reach patients who are currently untreated or not being treated properly • Self-treatment for motivated patients can be empowering • Looking forward to having an OTC statin available • May help the underinsured and the uninsured populations afford therapy	• Cholesterol management can be complex and needs physician direction • Patients generally lack enough knowledge to properly treat high cholesterol; not as simple a condition compared with recent OTC introductions for allergy and heartburn • Risk of inadequate treatment with OTC statins could lead to increased liability	• Currently not enough information, particularly regarding price, to form an opinion • The generic versions of Zocor and Pravachol (expected within 2 years) may be better priced than an OTC statin • Still considering compliance issues with OTC statins, particularly the impact of physician–patient interaction

Interview Question: "If an OTC statin should become available, do you believe more, less, or the same number of people will be on statins?"

The Number of "More" Versus "Same" Versus "Don't Know" Responses



** No one responded that "less" people would be on statins.*

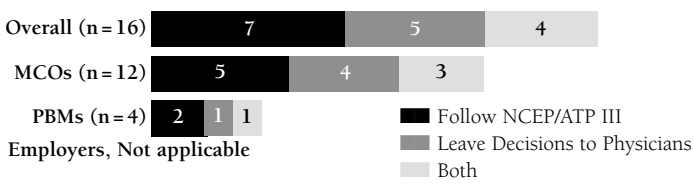
Reasons More People Will Be on Statins	Reasons the Same Number of People Will Be on Statins
• More convenient for people to obtain without a physician visit and prescription • Increased exposure will lead to increased requests for cholesterol tests and resultant therapy • Medicare patients may move to OTC statins as a lower-priced option to prescription versions	• Initial increased use of OTC statins but poor compliance will return utilization to near baseline levels • Increased utilization will depend on the recommendations of patient's physicians • Inability to track OTC use of members may negatively impact programs designed to identify candidates for therapy

Conclusion 2: Payer policies will continue to support access to prescription statins, and no change in policy is expected when an OTC option is available.

Currently, all MCOs and PBMs recommend following NCEP ATP III guidelines. Most participants noted that they do not determine policy and that they leave prescribing decisions to physicians. There is no indication that this practice will change with the availability of an OTC statin. Of the 18 organizations we interviewed, none reported that they would change policies for current prescription statin users. Employers typically follow the advice of their PBMs and do not get involved in medical policy or prescribing decisions.

Interview Question: "What is your current policy with regard to people who are at low, moderate, and high risk of heart disease?"

The Number Who Follow NCEP and ATP III Guidelines Versus the Number Who Leave Prescribing Decisions to Physicians



Interview Question: "When generic lovastatin was introduced, what changes or modifications did you make?"

The Number Who Changed Preferred/Nonpreferred Status and/or Copayment Tiers of Other Statins Versus the Number Who Made No Changes Other Than Adding Generic to its Generic Copayment Tier

Following the introduction of generic lovastatin, only 5 (31%) of the MCOs or PBMs made any changes to their formulary or copayment tiers of other branded statins. Most merely added generic lovastatin to their generic category, and all other drugs remained as they were. Those who made changes to copayment tiers moved branded drugs between second and third tiers, depending on price and manufacturer discounts.

Interview Question: "Would your policies for those on current Rx statins change should an OTC statin medication be approved by the FDA?"

The Number of "Yes" Versus "No" Answers

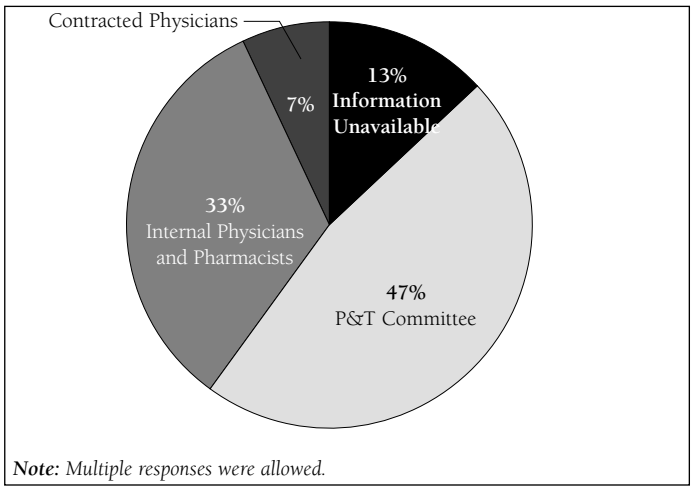
Participant observations support the view that an OTC statin would not negatively affect consumer access to prescription statins. Participants viewed statins as life-saving drugs, a different perception from the relief of symptoms achieved with Claritin and Prilosec. In addition, none of the participants plan to cover an OTC statin on their formulary, but note that pharmacy and therapeutics committees typically make drug coverage decisions. A few MCOs did mention that, depending upon the price of an OTC, they might review formulary placement of some branded prescriptions and possibly shift them to stratify and optimize the entire class. Others noted that, in addition to cost, the availability of generic lovastatin would play an important role in determining formulary placement.

Interview Question: "If an OTC statin medication was approved by the FDA, would you consider providing coverage for OTC statin utilization?"

The Number of "Yes" Versus "No" Answers

These MCOs and PBMs were unanimous in not covering an OTC statin. Most noted that employers are not looking to expand current drug offerings and instead are hoping to control drug trend. Legality, communication issues, and precedence (e.g., leading the pack and setting the example) were noted as reasons for not covering OTCs. In addition, self-insured employers did not want to deal with tax issues related to coverage of OTC drugs.

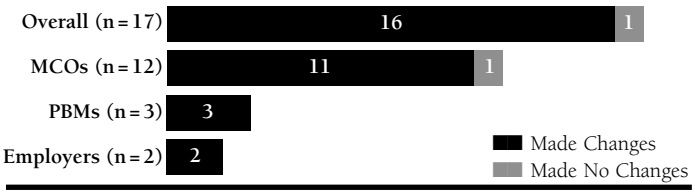
Interview Question: "Who reviews these types of programs and has decision-making authority within your organization?"



Note: *Multiple responses were allowed.*

Interview Question: "In light of the recent patent expiration for loratadine and the launch of OTC loratadine products, have you changed any coverage policies as a result?"

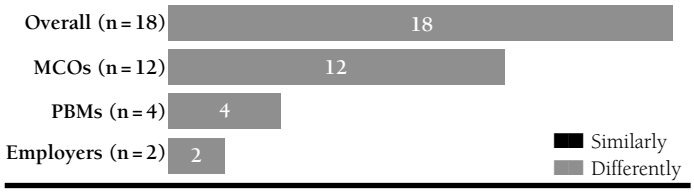
The Number Who "Made Changes" Versus "Made No Changes"



Most MCOs and PBMs reported eliminating coverage for Claritin when the drug company withdrew Claritin from prescription status and it became available OTC. In some cases, the MCOs and PBMs moved other nonsedating antihistamines to a nonpreferred formulary status. A few also implemented prior authorization requirements. As a result of these factors, plans typically witnessed a "significant" decrease in utilization. However, the payers view OTC statins differently from Claritin. The lack of a generic prescription version of Claritin also makes this situation unique.

Interview Question: "Do you believe an OTC statin would be viewed similarly or differently than Claritin or Prilosec?"

The Number Who View OTC Statin "Similarly" Versus "Differently"



Participants clearly view the statin category as unique relative to Claritin and Prilosec OTC, and the reasons included the following:

- As opposed to statins, Claritin and Prilosec provide episodic and symptomatic relief.
- Statins require ongoing compliance for effectiveness.
- Statins require ongoing monitoring for effectiveness and safety.
- Prilosec and Claritin can successfully treat nearly all patients. Other prescription statins would be required to successfully treat a significant percentage of patients.

Participants do not expect a significant shift of patients from prescription to OTC statins, as was seen during the Claritin OTC introduction.

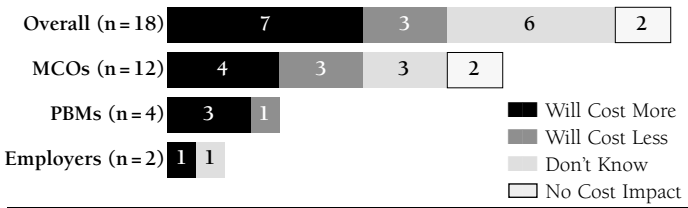
Conclusion 3: One third of the MCOs and 75% of the PBMs anticipate a sharp increase in plan costs as a consequence of OTC statin availability.

Participant opinions can be separated into short-term and long-term observations:

Short-Term Observations	Long-Term Observations
• Increased awareness of condition will drive people to doctors for testing • Some new users of OTCs will not be treated to goal and will need to see a doctor • Some OTC users could experience adverse reactions or side effects and require physician interaction • There is the potential for "perverse incentives" based on price of OTC versus copay for a generic or preferred brand prescription	• Access to an OTC may lower medical costs in the long-run by preventing cardiac events

Interview Question: "Do you envision any cost impact from offering some form of coverage for OTC statins?"

The Number Who Believe That Cost Impact Will Be "More" Versus "Less" Versus "Don't Know"



Why OTC Statins Will Cost More	Why OTC Statins Will Cost Less
• Increased awareness will lead to increased cholesterol testing • Initially, OTC versions often cost more than generic alternatives	• Increased use of an OTC statin for primary prevention could decrease major medical costs as a result of preventing major cardiac events • An OTC option eliminates physician costs and reduces copayments

Interview Question: "Do you have a certain threshold of savings that must be generated by covering OTC statins in order to drive your interest towards implementing this program?"

There was no common answer to this question. Most respondents were unable to answer as they believe the cost impact for an OTC statin would be negative (e.g., cost payers more), and some were unsure of the cost impact. Of those who did provide an answer to the question, thresholds ranged from 1% to 20% of savings. Part of the difficulty in answering this question is due to the uncertainty of the price of an OTC statin. Nearly every interviewee modified at least one of their answers with the caveat that "the price point of the OTC statin is critical."

Conclusion 4: Consumer/member reaction will be mixed and "DTC" (direct-to-consumer) advertising and physician education will be very important.

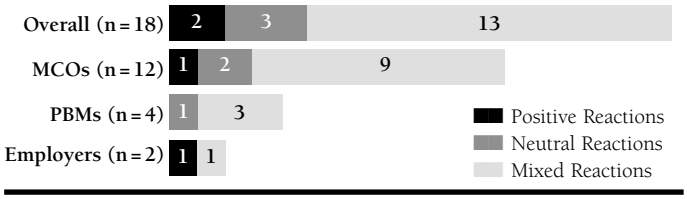
Nearly 50% of interview respondents reported that they would encourage or educate their members on the availability of an OTC option. Thirty percent of respondents noted they need more

	Anticipated Reactions	Underlying Reasons
Positive	• Members would like an OTC option if it saves them money • Members would like the option to self-treat	• Additional access to a drug with added convenience and elimination of a physician visit for a prescription and refill request • Increased public awareness and understanding of their options
Negative	• Likely negative reaction if the OTC version costs more than a copayment • Members may not have enough information to understand when they should use an OTC or a prescription statin	• Price point is critical. Most assume an OTC will cost more than the generic copay • Concern that members will be confused about an OTC option and will still need doctor supervision

information, such as the OTC price point relative to copayments, payer reactions (e.g., employers), and clinical evidence of treatment to goal and safety before determining how, or if, they would communicate the availability of an OTC statin to their members.

Interview Question: "What reactions, advantages, or potential issues do you anticipate arising among employee/members if you begin providing coverage for OTC statins?"

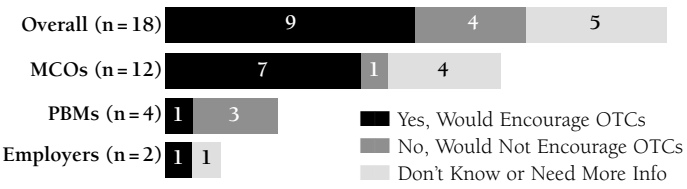
The Number of "Positive" Versus "Negative" Versus "Mixed" Responses



Most MCOs and PBMs believe members would have mixed reactions about an OTC option. Some would view it favorably and as an enhancement while others would view it as a benefit takeaway, especially if the OTC statin is more expensive than the generic prescription drug. Thus, the financial incentive would be very important.

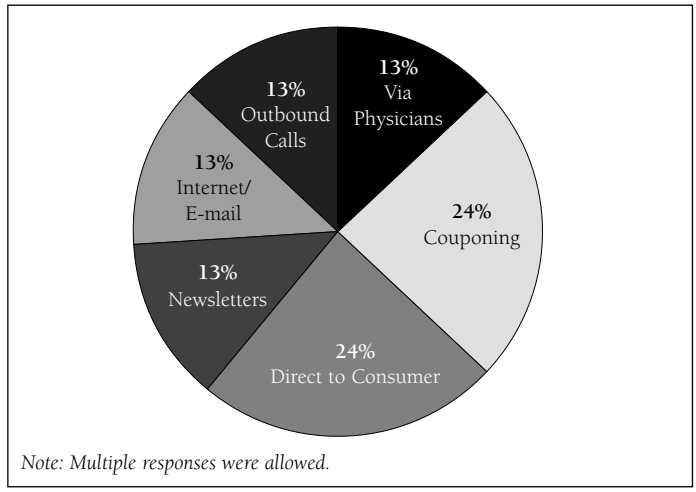
Interview Question: "If an OTC statin medication were approved by the FDA, would you consider encouraging OTC utilization within your member population?"

The Number of "Yes" Versus "No" Versus "Don't Know" Answers



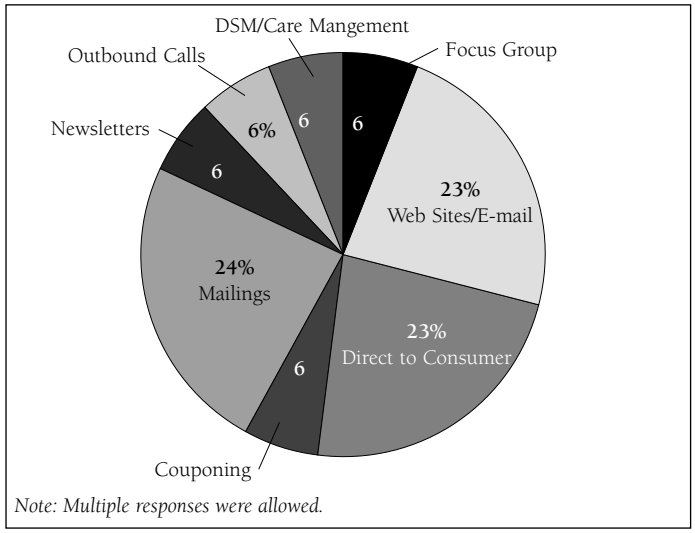
Reasons for Encouraging OTCs	Reasons Not to Encourage OTCs	Miscellaneous
• Prefer the term "educate", rather than "encourage" • Any type of program that can create awareness for people and alert them that an Rx-strength medication is available OTC can benefit members • Would likely introduce a coupon program to encourage OTC trials	• Programs to encourage OTC statins may result in member concerns of manufacturer payments to promote their drug • Some debate whether any statins should be covered • Concern over potential liability if recommending an OTC product to a patient who later has an adverse event	• Would only encourage OTC use if recommended by major organizations focusing on the treatment of heart disease and high cholesterol

Interview Question: "What would be the most effective manner to support appropriate usage of an OTC statin within the low and moderate risk group?"



Note: Multiple responses were allowed.

Interview Question: "What type of consumer education would you consider important to ensure your members understand an OTC benefit?"



Note: Multiple responses were allowed.

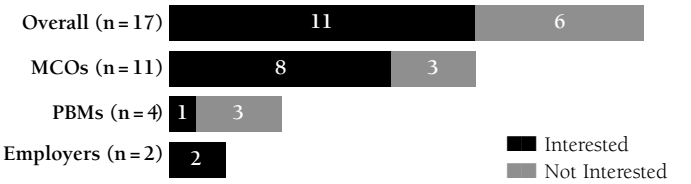
Conclusion 5: MCOs and PBMs are eager for involvement but cautious about "partnership."

There is concern about the perception of partnerships in light of the Office of Inspector General compliance guidelines focusing on limiting illegal marketing activities and the very large amount of media coverage of the relationships between PBMs and manufacturers.[12] Some participants worry that people may perceive the encouragement to use an OTC statin as MCOs forcing participants to self-diagnose and manage serious illness. However, many of the participants encouraged dialogue about OTC statins and the potential for FDA approval. Several participants expressed interest in obtaining current and

updated progress reports on the FDA approval status of an OTC statin. Should FDA approval be forthcoming, several also expressed interest in working with the manufacturer to educate physicians and members on OTC options.

Interview Question: "What is your level of interest in setting up a partnership with a retail chain, PBM or pharmaceutical manufacturer to administer an OTC benefit?"

The Number of "Interested" Versus "Not Interested"



Interested	Not Interested
• Partnership would focus on raising awareness, educating consumers, and providing an incentive to encourage members to try an OTC statin • Interested only if focused on improved health • Interested in working with a group of pharmacists to provide appropriate counseling or testing	• Do not partner with pharmaceutical manufacturers or accept their funding • If OTC statin is worth it, there will be no partnering required • Would partner with a pharmaceutical manufacturer only for a business necessity • Want to avoid any perception that pharmaceutical manufacturers unduly influence our decisions

Conclusion 6: The details of any OTC statin offering will lay the foundation for its success.

MCOs and PBMs need additional information to estimate the likelihood of success of an OTC statin. This information includes the following:

- How to improve patient compliance—this is considered a significant problem for patients taking prescription statins; participants generally expect less compliance for an OTC statin
- Price and total cost to treat—some participants believe an OTC statin would lead to increased program costs due to increased awareness and testing
- Effectiveness of self-monitoring programs—patients may not have enough knowledge to successfully manage their own therapy
- Consumer advertising approach

Interview Question: Additional thoughts and observations shared by participants:

- An OTC statin will revolutionize the statin industry and cholesterol therapy.
- An OTC statin presents a unique and different situation compared with Claritin or Prilosec. The pharmaceutical manufacturer will need to convince the FDA that most utilization will come from currently untreated patients with a need to lower their cholesterol.
- Competing pharmaceutical manufacturers will likely increase their advertising and counter-detailing efforts.

Survey Update

The original survey was conducted shortly after the introduction of Claritin OTC and prior to the introduction of Prilosec OTC. We believe these introductions could have influenced the participants' opinions regarding the introduction of an OTC statin. In July 2004, follow-up interviews were conducted with the same MCOs and PBMs to gauge whether or not perceptions had changed in the past 12 months. Eleven of the 16 were available for the follow-up interview. Findings from both research surveys were largely consistent.

We shared the original study findings with each participant, and all interviewees responded that they generally agreed with the collective conclusions. With the passage of a year and experience with additional Rx-to-OTC switches, interviewees contemplated some potential implications. Several interviewees observed that they might not see the increase in plan costs they had anticipated a year earlier. While awareness and interest would increase, one half of the interviewees were not as convinced an OTC statin would increase doctor or hospital visits. And because the MCOs and PBMs are unlikely to cover an OTC statin, plan costs might not increase as dramatically as originally thought.

Even with the recent revision of the ATP III guidelines and market advances such as the OTC launches of Claritin and Prilosec, interview participants confirmed that, overall, polices with regard to people in the low-, moderate-, and high-risk heart disease groups would not change. One interviewee who employs a generic-first program that educates physicians on available OTCs suggested that, similar to other OTC launches, they would include the OTC statin in this program. Another interviewee commented that more-aggressive employers might consider introducing an OTC statin into step-therapy but that as an organization, they were "lukewarm" on the idea.

With regard to coverage, participants speculated as to what other drug therapies might be available and possible implications to copayment-tier changes with the FDA approval of an OTC statin. With that context, several interviewees focused on the strength and efficacy of the statin as critical to any possible switch. For example:

- Should a higher potency OTC statin become FDA approved (not contemplated in the interview, but postulated by 2 respondents), they would consider adjustments to their tiering of statins over time.
- Should the approval be equivalent to current "low-potency" Rx statins (which represent fewer than 10% of prescriptions written for statins), a few would consider moving an equiv-

alent, low-potency Rx statin off formulary if it is available to members OTC and could potentially lower costs to the employer, employee, and administrator.
- All MCO and PBM survey participants continued to emphasize that they would encourage low-risk and moderate-risk members to use the OTC statins but would not likely cover the OTC statin on the prescription drug formulary.

Conclusions

Our research findings can be summarized into 6 key conclusions (1) participants generally view OTC statins as a beneficial addition to therapy; (2) payer policies will continue to support access to prescription statins, and no change in policy is expected when an OTC option is available; (3) two thirds of the MCOs and 75% of the PBMs anticipate a sharp, short-term increase in plan costs as a consequence of OTC statin availability; (4) consumer and member reaction will be mixed, and consumer advertising and physician education will be important; (5) MCOS and PBMs are eager for involvement but cautious about partnerships with pharmaceutical companies; and (6) the details of any OTC statin offering, including pricing, will lay the foundation for its success.

DISCLOSURES

Funding for this study was provided by Johnson & Johnson and Merck pharmaceutical companies and was obtained by author Steven Blumenfield. Blumenfeld and authors Ronald A. Lyon and Megan K. Richards were compensated for a study sponsored by the manufacturer. Richards served as principal author of the study. Study concept and design, analysis and interpretation of data, and statistical expertise were contributed by Richards and Blumenfield. Drafting of the manuscript was primarily the work of Richards and Lyon, and its critical revision was the work of all authors.

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