HMG-CoA Reductase Inhibitors (Statins)
Subcommittee Report

Update #1, September, 2003

This report is an update of the initial Statin Subcommittee Report of June, 2002. All revisions are highlighted.

Produced by:
Health Resources Commission
Kathleen Weaver, MD, Director
Office for Oregon Health Policy & Research
255 Capitol Street NE
Salem, OR 97310
Overview for Update #1

The 2001 session of the Oregon Legislature passed Senate Bill 819, authorizing the creation of a Practitioner-managed Prescription Drug Plan (PMPDP). The statute specifically directs the Health Resources Commission (HRC) to advise the Department of Human Services on this Plan.

In January of 2002 the HRC appointed a subcommittee to perform an evidence-based review of the use of 3-hydroxy-3-methylglutaryl-coenzyme (HMG-CoA) reductase inhibitors for the management of hypercholesterolemia. Members of the subcommittee consisted of physicians, pharmacists, nurse practitioners, other health care professionals, consumers and advocates. The subcommittee held eight meetings, two of which were general sessions of orientation and evidence-based analysis education. All meetings were held in public with appropriate notice provided.

Subcommittee members worked with Oregon Health and Science University’s Evidence-based Practice Center (OHSU-EPC) to develop and finalize key questions for drug class review, specifying patient populations, medications to be studied and outcome measures for analysis, considering both effectiveness and safety. Evidence was specifically sought for subgroups of patients based on race, ethnicity, age, demographics, other medications and co-morbidities.

Using standardized methods, the OHSU-EPC reviewed systematic databases, the medical literature and dossiers submitted by pharmaceutical manufacturers. Inclusion/exclusion criteria were applied to titles and abstracts, and each study was assessed for quality according to predetermined criteria.

The OHSU-EPC’s report titled “Drug Class Review on HMG-CoA Reductase Inhibitors (Statins)” was completed the week of May 13, 2002, circulated to subcommittee members and posted on the web. The subcommittee met on May 21, 2002, to review the document. By consensus, the subcommittee members agreed to adopt the report. Time was allotted for public comment, questions and testimony. At the subcommittee’s meeting on May 28, 2002, members of the HRC were invited to attend the meeting to clarify policy issues that were complicating decision-making for the subcommittee. Policy was discussed, then Commissioners were excused. Subcommittee deliberations continued but no final conclusions were drawn. The subcommittee next met on June 4, 2002. The final meeting was held on June 12, 2002, and final conclusions were drawn. Again, time was allowed for public testimony. All available sources of information; the OHSU-EPC report, which includes information submitted by pharmaceutical manufacturers, and public testimony were considered. The conclusions drawn by the Statins Subcommittee comprise the body of this report.
In January of 2003 the HRC appointed an Update Committee to perform an evidence-based review of the June 2002 HMG-CoA Reductase Inhibitors (Statins) Subcommittee Report for new information or changes in the Federal Drug Administration (FDA) package inserts. Members of the Update Committee consisted of one HRC member, one Oregon State University (OSU) College of Pharmacy pharmacist, one OHPR physician, one OHSU-EPC physician, and two Statin Subcommittee members. This report is an update of the initial June 2002 Statin Subcommittee Report. All revisions are highlighted.

The OHSU EPC’s report, “Drug Class Review on HMG-CoA Reductase Inhibitors (Statins) Update Report” was completed May 13, 2003, circulated to the Update Committee members and posted on the OHPR website at www.ohpr.state.or.us. The Update Committee determined there was significant new information to recommend convening the original Statin Subcommittee. The Statin Subcommittee and Update Committee met on July 29, 2003, and on August 20, 2003 to review the OHSU-EPC update report and additional evidence.

The Update Committee and Subcommittee members worked with the OHSU-EPC reviewing the evidence for both effectiveness and safety. Evidence was specifically sought for subgroups of patients based on race, ethnicity, age, demographics, other medications and co-morbidities. By consensus, the subcommittee and committee members agreed to adopt the OHSU-EPC report. Time was allotted for public comment, questions, and oral testimony. All available sources of information from the OHSU-EPC report that included information submitted by pharmaceutical manufacturers and public testimony, were considered.

This report is prepared to facilitate the HRC in providing recommendations to the Oregon Medical Assistance Program (OMAP) for the Plan Drug List (PDL). This report was presented to the HRC on September 26, 2003, at which time public testimony was heard and due consideration given. On September 26, 2003 this report was approved by the HRC and commended to OMAP. This update report does not recite or characterize all the evidence that was discussed by the OHSU-EPC, the Statin Update Committee, the Statin Subcommittee or the HRC. For further information provided during the committee process, readers are encouraged to review the source materials on the website.

The Statin Update Committee of the HRC, working together with the OHSU-EPC, OMAP, and the OSU College of Pharmacy, will continue to monitor medical evidence for new developments in this drug class. Approximately every six months emerging pharmaceuticals will be reviewed and if appropriate, a recommendation for inclusion in the PDL will be made. Significant new evidence for pharmaceuticals already on the PDL will be assessed and FDA changes in indications and safety recommendations will be evaluated. The Statin Subcommittee Report will be amended if indicated. Substantive changes will be
brought to the attention of the HRC, who may choose to approve the report, or reconvene the Statin Subcommittee.

The OHSU-EPC’s update report, “Drug Class Review on HMG-CoA Reductase Inhibitors”, is available on the Office for Oregon Health Policy & Research, Practitioner-Managed Prescription Drug Plan website: www.oregonrx.org. Information regarding the HRC and its subcommittee policy and process can be found on the OHPR website: www.ohpr.state.or.us. You may also request more information or minutes and tapes from committee meetings from:

Kathleen Weaver, MD
Director, Health Resources Commission
255 Capitol St. NE, 5th Floor
Salem, Oregon 97310
503-378-2422 ext. 227
kathy.weaver@state.or.us

Information dossiers submitted by pharmaceutical manufacturers are available upon request from OHSU-EPC by contacting:

Jeani Crichlow
Oregon Health & Science University
Mailcode: BICC
3181 SW Sam Jackson Park Road
Portland, OR 97201-3098
Phone: 503-494-4502
Fax: 503-494-4551
E-mail: crichlow@ohsu.edu

There will be a charge for copying and handling in providing documents from OHPR and from OHSU-EPC.

**Critical Policy:**

- **Senate Bill 819**
  - "The Department of Human Services shall adopt a Practitioner-Managed Prescription Drug Plan for the Oregon Health Plan. The purpose of the plan is to ensure that enrollees of the Oregon Health Plan receive the most effective prescription drug available at the best possible price."

- **Health Resources Commission:**
  - “Clinical outcomes the most important indicator of comparative effectiveness;"
“If evidence is insufficient to answer a question, neither a positive nor a negative association can be assumed.”

**Inclusion Criteria:**

- **Scope**
  - Adult patients targeted for primary or secondary prevention of coronary heart disease (CHD) or non-coronary forms of atherosclerotic disease with or without hypercholesterolemia. Children and rare, severe forms of Hypercholesterolemia (LDL-c greater than 250mg/dl) were excluded, as were studies in populations with acute coronary syndrome.

**Definition of HMG-CoA Reductase Inhibitors:**

- Atorvastatin (Lipitor)
- Fluvastatin (Lescol, Lescol XL)
- Lovastatin, (Mevacor)
- Extended Release Lovastatin (Altocor)
- Pravastatin (Pravachol)
- Simvastatin (Zocor)

**Key Questions:**

1. How do Statins compare in their ability to reduce LDL-c?

2. How do Statins compare in their ability to reduce the risk of non-fatal myocardial infarction, CHD (angina), CHD mortality, all-cause mortality, stroke or need for revascularization (coronary artery bypass graft, angioplasty or stenting)?

3. What is the correlation between LDL-c lowering and the risk reduction for clinical outcomes?

4. Are there differences in the efficacy or safety of Statins in different demographic groups (age, sex, race)?

5. Are there differences in the safety of Statins when used in special populations?
New Findings of Statin Update Committee 7/03

- The EPC received four dossiers from pharmaceutical manufacturers. This information was added to the material identified in our update search.
- Kathy Ketchum, RPh, OSU College of Pharmacy reported:
  - The release of an extended action lovastatin (Altocor) on 6/26/02.
  - The addition of one new drug, rosuvastatin (Crestor) approved August 12, 2003.
  - The FDA has revised its labeling of atorvastatin, lovastatin, and simvastatin to include an indication in children and adolescents with a familial dyslipidemia.
  - The FDA has added more detailed warnings about liver enzyme elevation and skeletal muscle damage that are standard for statins.
  - Fluvastatin has new product label pertaining to the pharmacokinetics of extended-release fluvastatin (Lescol XL) posted April 23, 2003
- Using the same search strategy from the original Statin report, the EPC found 107 new citations published in 2002 or 2003 that were not cited in their original report. Of these, 21 were controlled trials and 11 were potentially eligible reviews and meta-analyses.
- A separate search for rosuvastatin studies identified 10 controlled trials, of which 7 were head-to-head trials or meta-analyses. Several of the head-to-head rosuvastatin trials included two or more active controls (e.g. pravastatin and simvastatin), making them eligible to be included in the head-to-head trials even if rosuvastatin itself is not examined in this update.
- The completion of the Heart Protection Study (HPS) trial of 20,536 patients with simvastatin vs. placebo was associated with a 27% relative reduction in coronary events (NNT=32) and of stroke. In subgroups simvastatin 40 mg was effective in primary prevention of CHD in patients with diabetes (NNT=24 to prevent a major event in 5 years) and in patients with a history of peripheral or carotid atherosclerosis, but not CHD. These reductions were observed in women, individuals over or under age 70, and those with a total cholesterol <200mg/dl and LDL-c <120mg/dl.
- The Anglo-Scandinavian Cardiac Outcomes Trial Lipid Lowering Arm (ASCOT-LLA) that was a subset of 10,305 patients randomized to atorvastatin or placebo was prematurely stopped after a median follow-up of 3.3 years because of a 36% difference in non-fatal myocardial infarction (which includes silent myocardial infarction) and fatal coronary heart disease. This trial also provides new information on the relationship between the degree of lipid-lowering effect and the degree of reduction in cardiovascular events. In addition this trial describes unprecedented large numbers of older patients >65, women, African-Americans and patients with diabetes treated largely in community practice settings.
- The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack-Lipid-lowering Arm (ALLHAT-LLC) trial of pravastatin for primary
prevention was a fair quality, open-label randomized controlled trial (RCT) of 10,355 hypertensive patients randomized to pravastatin 40 mg or to usual care. Nearly half the subjects were women, 35% were diabetic, 15% had a history of coronary heart disease (CHD) and about 35% were black.

- The PROSPER trial, with an overall good-quality rating, was designed to examine the benefits of statin therapy in women and the elderly. Of the 23,770 patients screened, 16,714 were ineligible or refused to participate. This trial had a pre-randomization run-in period during which noncompliant subjects were excluded from randomization. Of the 7,056 who entered the run-in period 82% were randomized.

- The Lescol Intervention Prevention Study (LIPS) has been completed after being cited in abstract form in the first Statin Report. It is a study of 1055 patients who previously had undergone angioplasty or other percutaneous coronary intervention (PCI) were randomized to fluvastatin 40 mg bid or placebo for 4 years. There was a 22% relative reduction (p=0.0127, NNT=19) of major coronary events in the fluvastatin group. Diabetics and patients with multivessel disease experienced a comparable or greater benefit with fluvastatin compared to the controls.

- Although the Holdaas report had limited number of patients (2102), it is significant because of its length of treatment (5 years) for fluvastatin in renal transplant patients.

**Summary of Results (changes highlighted)**

1. **HOW DO STATINS COMPARE IN THEIR ABILITY TO REDUCE LDL-c?**

   A. *Are there doses for each statin that produce similar percent reduction in LDL-c between Statins?*

   Forty-four randomized clinical trials compared the LDL-c lowering ability of two or more Statins in patients with baseline LDL-c greater than 250 mg/dl. In twenty-five of the trials, the NCEP goal was also evaluated. In almost all, the mean percent LDL-c reduction for a particular Statin dose showed little variation across studies. From these data, approximate equivalent daily doses for Statins with respect to their LDL-c lowering abilities were determined. The EPC estimates based on head-to-head trials were consistent with the actual values from a more recent meta-analysis of placebo-controlled trials.

   Two studies directly compared atorvastatin 80 mg and simvastatin 80 mg daily with atorvastatin showing a reduction of LDL-C by 53.6% compared to simvastatin 48.1% (p<0.001) in one and 53% to 47% in the other (p<0.0001).

   B. *Is there a difference in the ability of a Statin to achieve National Cholesterol Education Panel (NCEP) goals?*
Problems in equivalent dosing limit the validity of many of the twenty-six trials that met inclusion criteria and reported the percentage of patients achieving NCEP goals. In some head-to-head comparisons, the maximal recommended dosage was not reached by the "inferior" drug.

A recent meta-analysis by Shepherd of five 12 week studies was designed to evaluate rosuvastatin, but allowed indirect comparison of atorvastatin 10 mg, simvastatin 20 mg and pravastatin 20 mg. Fifty-three per cent of patients taking atorvastatin 10 mg reached their ATP III goals vs. 64% for simvastatin and 49% for pravastatin. Comparing these results to those of the head-to-head comparisons of atorvastatin and simvastatin, simvastatin performed better than atorvastatin in studies conducted by the maker of rosuvastatin.

There is fair-to-good evidence that for patients who require LDL-c reductions of up to 40% to meet their goal, all Statins are effective. There is fair to good quality evidence that for patients requiring an LDL-c reduction of 40% to 49%, atorvastatin 20 mg or greater, lovastatin 80 mg, or simvastatin 40 mg or greater are likely to meet this goal. Atorvastatin at a dose of 80 mg can achieve a reduction of LDL-c between 50-54%, but had significantly higher rates of adverse events.

The subcommittee concludes by consensus that all Statins in equipotent doses are effective to reduce LDL-c up to 40%. To achieve a goal of LDL-c reduction of 40-49%, there is evidence that atorvastatin, lovastatin and simvastatin are effective. Only atorvastatin at doses of 40 mg or higher can achieve a reduction of 50% or greater.

2. HOW DO STATINS COMPARE IN THEIR ABILITY TO REDUCE THE RISK OF NON-FATAL MYOCARDIAL INFARCTION, CHD (ANGINA), CHD MORTALITY, ALL-CAUSE MORTALITY, STROKE OR NEED FOR REvascularization (CORONARY ARTERY BYPASS Graft, angioplasty OR STENTING)?

No good quality controlled trials directly compared the ability of two or more Statins to reduce the risk of coronary events, stroke or death. Many trials compared a Statin to placebo. Thirty-one trials meeting criteria for inclusion reported cardiovascular outcomes in patients randomized to receiving a Statin compared to placebo control.

Nine large multi-center first tier studies designed to assess cardiovascular health outcomes in patients without known CHD, compared a Statin with placebo. All
studies showed relative reduction in coronary events, and three studies reported absolute reductions in coronary events.

Twelve second-tier studies had a primary endpoint of progression of atherosclerosis and also reported rates of coronary or cardiovascular events. All patients had known CHD. The studies were fair-to-poor quality. Evidence about fluvastatin showing significant reduction in CHD events was inconclusive. Evidence for lovastatin, pravastatin and simvastatin was already known from tier one studies.

Six third tier studies of reduction of CHD in re-vascularized patients were of fair or fair-to poor quality. These studies were small and the endpoint was generally the rate of re-stenosis.

Five other studies that reported health outcomes that did not fit into the first two tiers were included in the third tier as "miscellaneous" trials.

First tier studies provide consistent good-quality evidence that atorvastatin, lovastatin, pravastatin and simvastatin reduce cardiovascular events. Atorvastatin has good quality evidence that it reduces coronary events in primary and secondary prevention trials. Pravastatin, simvastatin and lovastatin have good-quality evidence for both primary and secondary prevention. Pravastatin and simvastatin have good quality evidence for secondary prevention and also reduced deaths from cardiac disease. Three separate studies showed that the risk of stroke was significantly reduced in the secondary prevention trials for atorvastatin, pravastatin, and simvastatin. Only one-third tier post-revascularization study and one miscellaneous study provided fair evidence about the efficacy of fluvastatin.

The subcommittee concludes by consensus that there is good quality evidence for improved cardiac outcomes with atorvastatin, fluvastatin, lovastatin, pravastatin and simvastatin when compared with placebo. There is also good quality evidence for reduction of risk of stroke with atorvastatin, pravastatin and simvastatin when compared with placebo. There are no studies, which directly compare the efficacy of different statins in the reduction of cardiovascular events.

3. WHAT IS THE CORRELATION BETWEEN LDL-C LOWERING AND THE RISK REDUCTION FOR CLINICAL OUTCOMES?

The question was asked whether the relationship between LDL-c lowering and cardiac events was consistent across studies, reasoning that if it were consistent, it
might be inferred that a Statin which has been proven to reduce LDL will also reduce coronary events even if it hasn’t been demonstrated to significantly effect cardiovascular outcomes in good quality randomized trials.

The question could not be answered by the best quality prevention trials because of differences in their inclusion criteria and baseline risk. Unknown factors, small number of efficacy studies, population differences and definitions of coronary events make statistical analysis potentially misleading. Meta-analyses of existing Statin trials do not provide a clear answer. Differences in risk reduction among studies depend much more on the characteristics of the subjects than on the degree of LDL-c lowering. The case for extrapolating results from one Statin to another, or one population to another cannot be based on the statistical relationship between LDL-c lowering and the magnitude of benefit, though every large, multicenter primary or secondary prevention study has shown a benefit, regardless of the Statin used. While there is a relationship between LDL-c lowering and outcomes in a general sense, data are insufficient to quantify this relationship and other effects cannot be excluded.

The subcommittee concludes by consensus that there is good quality evidence for a benefit to lowering LDL-c. There is no consistent statistical relationship from trials reporting health outcomes between amount of LDL-c reduction and risk reduction. With current evidence, extrapolation of the degree of lipid lowering magnitude of changes in coronary heart disease outcomes cannot be made.

4. ARE THERE DIFFERENCES IN THE EFFICACY OR SAFETY OF STATINS IN DIFFERENT DEMOGRAPHIC GROUPS (AGE, SEX, RACE)?

A. Efficacy in Demographic Subgroups

Women and the Elderly: A meta-analysis of five large, long-term, primary and secondary prevention trials provides good evidence that Statins are efficacious in men, women and persons over age 65. An observational study in the elderly showed risk reduction in all ten-year age groups from age 60 to age 100. While it is clear from the HPS that women can benefit from simvastatin, in most of the other trials, risk reduction was smaller or non-existent in women, possibly because there were fewer women and they have an inherently lower risk than men.

African-Americans: African-Americans have the greatest overall CHD mortality and the highest out-of-hospital coronary death rates of any other
ethnic group in the US. Of the 27 trials reporting clinical events, only one provided numbers of participating African-American, and events were not analyzed by racial group. There is no evidence whether Statins differ in their ability to reduce CHD events in this population.

The subcommittee concludes by consensus that all Statins are effective in men, women and the elderly. There is no evidence supporting differences in efficacy in other demographic populations.

**B. Safety in Demographic Subgroups**

All of the statins used in the major long-term trials were tolerated equally well among men, women, and healthy elderly subjects. In a large observational study of lovastatin; men, women and the elderly experienced similar rates of adverse effects. The rates of myopathy and liver enzyme elevations increased with increasing doses of lovastatin, but did not differ among men, women, and healthy elderly subjects. A meta-analysis of randomized trials of simvastatin 80 mg had similar results.

A subgroup analysis examined the safety of lovastatin vs. placebo in African Americans. There was a significantly higher incidence of creatine kinase (CK) elevation in African-Americans compared to white Americans, but this was true in both the placebo and lovastatin treatment groups. No cases of myopathy, defined as CK elevations of >10 X the upper limit of normal occurred in African Americans.

The subcommittee concludes by consensus that based on available evidence there is no reason to believe that safety differences exist in women, the elderly, or other demographic populations including African-Americans.

**5. ARE THERE DIFFERENCES IN THE SAFETY OF Statins WHEN USED IN SPECIAL POPULATIONS?**

*Populations considered: Diabetics; patients with HIV; organ transplant patients; patients at high risk for myotoxicity; patients at high risk for hepatotoxicity.*
Special Populations and Safety:

Diabetics: Post-hoc subgroup analyses evaluated the benefits of Statins in reducing the risk of major coronary events in patients with diabetes and/or with impaired fasting glucose. In sixty-seven trials reviewed there was no data to support any additional safety concerns in diabetics compared to non-diabetics, though no evidence specifically addressed this question. Although the outcome measures were not uniform across studies, there were trends of statistically significant reduced overall mortality and/or major CHD events and revascularizations in patients treated with simvastatin and pravastatin.

Organ Transplant Recipients: The Holdass study presents good evidence that fluvastatin has long term (over 5 years) safety in renal transplant patients. Based on pharmacologic information, case reports and small series of patients, Statins, when used in the lowest doses, have safety profiles for transplant patients similar to the general population.

HIV Patients: A significant portion of HIV patients have medication-induced hyperlipidemia. There are no prospective randomized clinical trials evaluating the benefits of Statins in HIV patients; however, the Adult Aids Clinical Trials Research Group (AACTG) Cardiovascular Disease Focus Group and the Centers for Disease Control and Prevention (CDC)/Henry J Kaiser Foundation have made recommendations regarding the use of Statins in HIV infected individuals receiving protease inhibitors. Recommendations are based primarily on pharmacologic similarities in how proteases and most HMG-CoA reductase inhibitors are metabolized and are not evidence-based.

Myotoxicity and Hepatotoxicity:

Myotoxicity: There is a significant increase in relative risk for myopathy when Statins are used. The absolute risk remains very small for all Statins. Conclusions cannot be made regarding difference in risk of severe muscle toxicity between the Statins. All have rarely caused rhabdomyolysis, and in the majority of cases an additional drug with a potential for increasing the serum Statin level was identified.

Myopathy in Statin-Fibrates rate Combination: Because of the nature of adverse effect reporting and the available evidence, the answer to the question of whether one statin is safer than another with regard to combination with a fibrate is unknown. The FDA has approved recommendations combining a Statin with a fibrate or niacin.

Hepatotoxicity of Statins: All of the Statins are rarely associated with clinically important elevations of liver transaminases. No evidence supports a significant difference in the rates of clinically relevant elevations in liver enzymes between Statins.
The subcommittee concludes by consensus that:

- In shorter-term studies there is no evidence to suggest that Statins differ in their safety in diabetic patients. Furthermore, long-term studies have shown that atorvastatin, fluvastatin, lovastatin, pravastatin and simvastatin can be used safely in patients with diabetes and impaired fasting glucose.

- In organ transplant patients or patients with HIV, consideration of drug interactions between statins and immunosuppressants or protease inhibitors is important.

- In a single good quality long-term study, fluvastatin demonstrated tolerability in renal transplant patients.

- While there are no prospective randomized clinical trials evaluating the benefits of Statins in HIV patients, two groups of experts recommend using atorvastatin, fluvastatin or pravastatin in HIV infected individuals receiving protease inhibitors. These recommendations are based on potential drug interactions between protease inhibitors and those Statins that are metabolized through the cytochrome P-450 3A4 enzyme system. Fluvastatin and Pravastatin are not metabolized through this system.

- The current evidence reviewed for this report does not demonstrate a difference in liver toxicity and myotoxicity at equipotent doses.

**Conclusion (changes highlighted)**

In a series of public meetings with the opportunity for public questions, comment and testimony, the Statin Update Committee and Subcommittee of the HRC, reviewed the medical evidence comparing HMG-CoA reductase inhibitors for lipid lowering. All available sources of information including OHSU-EPC’s update report, “Drug Class Review on HMG-CoA Reductase Inhibitors,” and additional information presented in public testimony were considered. Using all available sources of information, the Subcommittee came to conclusions about the comparative effectiveness and safety of HMG-CoA Reductase Inhibitors in their ability to reduce the risk of nonfatal myocardial infarction, CHD (angina), CHD mortality, all-cause mortality, stroke or the need for revascularization.
(coronary artery bypass graft, angioplasty, or stenting) as supported by analysis of the medical literature:

It is the decision of the HRC Statin Subcommittee that:

1. Evidence supports the ability of atorvastatin, fluvastatin, lovastatin, pravastatin and simvastatin to improve coronary heart disease clinical outcomes.

2. No evidence supports differences between Statins in adverse effects in sub-populations by race and ethnicity, age, or gender.

3. Even though evidence does not determine a consistent statistical relationship between intermediate outcomes (LDL-c lowering) and specific CHD outcomes, the studies do allow a conclusion to be drawn that a benefit exists for lowering LDL-c.

4. Although experts recommend pravastatin, atorvastatin and fluvastatin in HIV infected individuals receiving protease inhibitors, there are no good quality studies that have looked at the safety of statins in this population.

5. Consideration of drug interactions with immunosuppressants in organ transplant patients is important. In a single good quality long-term study, fluvastatin demonstrated tolerability in renal transplant patients.
Frank Baumeister, Jr., MD  
Chair, Health Resources Commission

Diane Lovell  
Vice Chair, Health Resources Commission

Terri Bianco, PharmD  
Chair, Statins Subcommittee

Bruce Goldberg, MD  
Administrator  
Office for Health Policy & Research

Kathleen Weaver, MD  
Director, Health Resources Commission  
Office for Health Policy & Research

Health Resources Commission  
Frank Baumeister, JR., MD  
Diane Lovell  
Brad Bowman, MD  
Steven DeLashmutt, MD  
Elaine Dunda  
Dean Haxby, PharmD  
Dan Kennedy, RPh  
Walter Shaffer, MD  
Paul R. Tiffany  
Joanna Zamora, RN

Statins Subcommittee Members  
Lester Baskin, MD  
Terri Bianco, PharmD  
Rich Clark, MD  
Dan Gilden, MD  
Meg Hayes, MD  
Meera Jain, MD  
J. (Jack) Jackson, MD  
Chris Kirk, MD  
Mary Lawrence  
Allen Oyler, JD, MS  
Jim Slater, PharmD  
LouAnn Thorsness, PharmD

Update Committee Members  
Kathleen Weaver, MD  
Brad Bowman, MD  
Mark Helfand, MD, MPH  
Kathy Ketchum, RPh, MPA:HA  
Richard Clark, MD, MPH  
J. (Jack) Jackson, MD  
Terri Bianco, PharmD
Health Resources Commission

The State of Oregon’s Health Resources Commission is a volunteer commission appointed by the Governor. The Health Resources Commission provides a public forum for discussion and development of consensus regarding significant emerging issues related to medical technology. Created by statute in 1991, it consists of four physicians experienced in health research and the evaluation of medical technologies and clinical outcomes; one representative of hospitals; one insurance industry representative; one business representative; one representative of labor organizations; one consumer representative; two pharmacists. All Health Resources Commissioners are selected with conflict of interest guidelines in mind. Any minor conflict of interest is disclosed.

The Commission is charged with conducting medical assessment of selected technologies, including prescription drugs. The Commission may use advisory committees or subcommittees, the members to be appointed by the chairperson of the Commission subject to approval by a majority of the Commission. The appointees have appropriate expertise to develop a medical technology assessment. Subcommittee meetings and deliberations are public, where public testimony is encouraged. Subcommittee recommendations are presented to the Health Resources Commission in a public forum. The Commission gives strong consideration to the recommendations of the advisory subcommittee and public testimony in development of final reports.