Oregon Health Resources Commission

Agents for Overactive Bladder

Subcommittee Report

Update #3, January 2006

This report is an update of the initial
Urinary Incontinence Subcommittee Report of February 2003.
All revisions are highlighted.

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Overview

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

In November of 2002 the Oregon Health Resources Commission (HRC) appointed a subcommittee to perform an evidence-based review of the use of urinary incontinence drugs. Members of the subcommittee consisted of physicians, a pharmacist, a registered nurse, a nurse practitioner, other health care professionals and a consumer. The subcommittee had four meetings. All meetings were held in public with appropriate notice provided.

Subcommittee members worked with Oregon Health and Science University's (OHSU) Evidence-based Practice Center (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 and age, demographics, other medications and co-morbidities.

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

The OHSU's EPC report, "Drug Class Review on Urinary Incontinence" was completed the week of February 10, 2003, circulated to subcommittee members and posted on the web. The subcommittee met on March 3, 2003, to review the document and additional evidence. By consensus, the subcommittee members agreed to adopt the EPC report. Time was allotted for public comment, questions and testimony. The subcommittee's final meeting was held on April 16, 2003 to review the draft subcommittee report. All available sources of information including the EPC report, information submitted by pharmaceutical manufacturers, and public testimony were considered. The conclusions drawn by the Urinary Incontinence Subcommittee comprise the body of this report.

The HRC appointed a Standing Update Committee to perform an evidence-based review of the April 2003 *Urinary Incontinence Subcommittee Report* for new information or changes in the FDA package inserts. Members of the Standing Update Committee consisted of one HRC member, one OSU pharmacist, one Oregon Health Policy and Research (OHPR) physician, one OHSU-EPC pharmacist, and two physicians, one of which served on the original subcommittee. This report is the second update of the initial April 2003 Subcommittee Report. All revisions are highlighted.

The Standing Update Committee members worked with the OHSU-EPC reviewing the evidence for both effectiveness and safety. Evidence was specifically sought for differences among subgroups of patients based on race, ethnicity, age, demographics, other medications and co-morbidities.

The OHSU EPC's report, *Drug Class Review on Over Active Bladder Drugs Updated Final Report#2* was completed in May 2005 then circulated to committee members. The Standing Update Committee held two meetings June 7 and July 12, 2005 to review the document and additional evidence. By consensus, the committee members agreed to adopt the EPC report. Time was allotted for public comment, questions, and written and oral testimony. All available sources of information from the EPC's report that included information submitted by pharmaceutical manufacturers and public testimony, were considered.

The OHSU EPC's report, *"Drug Class Review on Over Active Bladder Drugs Updated Final Report#3"* was completed in December 2005 then circulated to committee members. The Standing Update Committee, including two members of the original Urinary Incontinence Subcommittee, held meetings on January 10, 2006 and February 7, 2006 to review the document and additional evidence. By consensus, the committee members agreed to adopt the EPC report. Time was allotted for public comment, questions, and written and oral testimony. All available sources of information from the EPC's 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 February 17, 2006 at which time public testimony was heard and due consideration given. On February 17, 2006 this report was approved by the HRC and commended to OMAP.

This report does not recite or characterize all the evidence that was discussed by the OHSU EPC, the Over Active Bladder Subcommittee or the Health Resources Commission. This report is not a substitute for any of the information provided during the subcommittee process, and readers are encouraged to review the source materials. This report is prepared to facilitate the Health Resources Commission in providing recommendations to the Department of Human Services.

The Over Active Bladder Subcommittee of the Health Resources Commission, working together with the EPC, OMAP, and the Oregon State University College of Pharmacy, will monitor medical evidence for new developments in this drug class. Approximately every year new pharmaceuticals will be reviewed and if appropriate, a recommendation for inclusion in the PMPDP will be made. For pharmaceuticals on the plan, significant new evidence will be assessed and Food and Drug Administration changes in indications and safety recommendations will be evaluated.

The full OHSU Evidence-based Practice Center's draft report, *Drug Class Review on Over Active Bladder Drugs* is available on the Office for Oregon Health Policy & Research, Practitioner-Managed Prescription Drug Plan website:
http://egov.oregon.gov/DAS/OHPPR/ORRX/HRC/evidence_based_reports.shtml

Information regarding the Oregon Health Resources Commission and its subcommittee policy and process can be found on the Office for Oregon Health Policy & Research website:
http://egov.oregon.gov/DAS/OHPPR/ORRX/HRC/process.shtml
You may request more information including copies of the draft report, minutes and tapes of subcommittee meetings, from:

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Information dossiers submitted by pharmaceutical manufacturers are available upon request from the OHSU Center for Evidence-based Policy by contacting:

John Santa, MD
Assistant Director for Health Projects
OHSU - Center for Evidence-based Policy
2611 SW 3rd Avenue, MQ 280
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There will be a charge for copying and handling in providing documents both from the Office of Oregon Health Policy & Research and the Center.

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 are the most important indicators of comparative effectiveness";
  - "If evidence is insufficient to answer a question, neither a positive nor a negative association can be assumed."

Inclusion Criteria:

- *Scope*

  Patients: Adult patients with symptoms of urge incontinence/ overactive bladder (urgency, frequency, leakage, dysuria).

- *Interventions*

  - Interventions include an anticholinergic incontinence drug compared with another anticholinergic incontinence drug, another drug, or placebo. Anticholinergic incontinence drugs include: oxybutynin, tolterodine, flavoxate (*immediate release, transdermal, and long-acting* formulations), trospium chloride, darifenacin and solifenacin which were approved since the previous update. The older hyoscyamine and scopolamine transdermal were used as comparators.

- *Efficacy Measures*

  - The primary efficacy measures are: mean number of incontinence episodes/24 h (*mean and change in mean*), number of micturitions/24 h (*mean and change in mean),* pad usage, subjective patient assessments of symptoms i.e. severity of problems caused by bladder symptoms, extent of perceived urgency, global evaluation of treatment and quality of life.

  - For effectiveness, randomized controlled trials and crossover trials were included.

- *Safety Measures*

    - The primary outcome measures for adverse effects: overall withdrawals, withdrawals, due to adverse effects, specific adverse effects or withdrawals due to specific adverse events, for example, dry mouth

    - For adverse effects, controlled clinical trials or observational studies were included. Drug-drug interaction studies of shorter duration will be included.

Exclusions:

- No original data: Paper does not contain original data (e.g. non-systematic review, editorial, letter with no original data). Good quality systematic reviews will be used as appropriate to inform the current view.

- Studies of multiple interventions (e.g. bladder training plus medication) in which the effect of the anticholinergic urinary incontinence drug cannot be delineated.

Drugs:

- *Urinary Incontinence Anticholinergic Drugs:*

Generic	**Brand**
– Darifenacin	Enablex
▪ Flavoxate	Urispas
▪ Hyoscyamine	Hyoscyamine
▪ Oxybutynin	Ditropan
▪ Extended release oxybutynin	Ditropan XL
▪ Scopolamine transdermal	Transderm Scop
▪ Solifenacin	VESicare
▪ Transdermal oxybutynin	Oxytrol
▪ Tolterodine	Detrol
▪ Extended release tolterodine	Detrol LA
▪ Trospium chloride	Sanctura

Key Questions:

1. For adult patients with urinary urge incontinence/overactive bladder, do anticholinergic incontinence drugs differ in efficacy?
    a. In head-to-head trials of anticholinergic drugs what is the comparative efficacy?
    b. What is the comparative efficacy of anticholinergic OAB drugs across active and placebo controlled trials?

2. For adult patients with urinary urge incontinence/overactive bladder, do anticholinergic incontinence drugs differ in safety or adverse effects?

3. Are there subgroups of patients based on demographics (age, racial groups, gender and long-term care residents), other medications, or co-morbidities for which one OAB drug is more effective or associated with fewer adverse effects?

New Findings

- Using the same search strategy as was used in the original Urinary Incontinence report, the EPC found 380 new citations with the four additional drugs. Of these, only 11 new trials met inclusion criteria - 3 new head-to-head trials, 6 placebo-controlled trials, 2 drug vs non-drug trials. Two systematic reviews, 3 post-hoc analyses of previously reviewed head-to-head trials, and 5 observational studies were also included.
- Trospium was approved in May 2004, with the approved indication being overactive bladder with symptoms of urge incontinence, urgency, and frequency.
- Darifenacin and solifenacin were approved 12/22/04 and 11/19/04.
- There are still no effectiveness trials of OAB drugs. Most of the RCTs had fair internal validity, but their applicability to community practice was difficult to determine. These studies generally excluded patients who would have been at risk of serious adverse events from anticholinergic drugs.
- Of those studies that stated the funding source, all were funded by the pharmaceutical industry, and industry employees often served as co-authors.

Amended Summary of Results

Key Question 1. For adult patients with urinary urge incontinence/overactive bladder, do anticholinergic incontinence drugs differ in efficacy?

1a. In head-to-head trials of anticholinergic OAB drugs what is the comparative efficacy?

Twenty-four head-to-head randomized controlled trials comparing oxybutynin, extended-release oxybutynin, tolterodine, trospium, flavoxate solifenacin and/or darifenacin were evaluated. In addition, one re-analysis of a subgroup from a previously reported study was included.

Oxybutynin IR vs Tolterodine IR

Four trials of fair quality comparing the immediate release (IR) formulations of oxybutynin and tolterodine did not demonstrate any significant differences in objective or subjective efficacy measures.

Oxybutynin ER vs Oxbutynin IR & Tolterodine ER vs Tolterodine IR

Four trials comparing oxybutynin extended-release (ER) to oxybutynin IR and one trial comparing tolterodine ER to tolterodine IR did not demonstrate any significant differences in efficacy. Additionally, one trial comparing oxybutynin transdermal (TD) to oxybutynin IR over 6 weeks did not find significant differences in objective or subjective measures among the two formulations.

Oxybutynin ER vs Tolterodine IR & Tolterodine ER vs Oxybutynin IR

In one fair quality study comparing oxybutynin ER to tolterodine IR, oxybutynin ER was significantly more effective in reducing the number of incontinence episodes/week and micturitions/week than tolterodine IR. Results were not analyzed according to an intent-to-treat analysis and the study was biased toward subjects who tolerated oxybutynin ER. The EPC and subcommittee, therefore, questioned whether an intent-to-treat analysis that would consider drop-outs due to lack of efficacy and adverse events, would result in the same findings. Another trial comparing tolterodine ER to oxybutynin IR did not find significant differences in objective or subjective efficacy measures or quality of life.

Oxybutynin ER vs Tolterodine ER

Two trials compared the ER formulations of oxybutynin and tolterodine. The OPERA trial did no find significant differences among the drugs in the primary outcome measure, mean change of urge incontinence episodes/week, and several secondary outcomes (mean change in total incontinence episodes/week, mean

change in micturitions/week). However, the trial did report a significant difference in the percent of continent patients at week 12 favoring oxybutynin ER. In one fair quality trial comparing tolterodine ER to oxybutynin ER, tolterodine ER was found to be more effective than oxybutynin ER in reducing subjective outcome measures such as patient-reported symptoms. However, concerns regarding the study design where centers were assigned to one drug based on local prescribing patterns and differences existed among the study populations, raise questions about the strength or validity of the conclusions.

Oxybutynin vs Trospium

Two trials compared immediate release formulations of oxybutynin to trospium. One trial was sponsored by a company that makes trospium, the other did not report sponsorship. One trial involving trospium and oxybutynin showed no significant difference between these drugs in patients with a spinal cord injury.[1] Another trial comparing trospium BID and oxybutynin IR BID over 54 weeks found no significant differences for micturition frequency, incontinence episodes or urgency episodes.[2]

Solifenacin vs Tolterodine

One fair quality study comparing solifenacin 5mg, solifenacin 10mg, or tolterodine IR 2 mg to placebo found that both solifenacin doses and tolterodine produced significantly lower mean number of micturitions/24 hours than placebo. Statistically significant reductions of urgency incontinence and total incontinence were seen with solifenacin compared with placebo, but tolterodine IR was not found to be different from placebo. In a post-hoc exploratory analysis, both doses of solifenacin were superior to tolterodine in reducing urge episodes while only the 10 mg dose of solfienacin was superior to tolterodine in reducing micturitions/24 hours.

The **STAR** trial[3] compared tolterodine ER 4 mg to a flexible dose of solifenacin (5mg or 10 mg) over 12 weeks. This study did not find differences in the primary endpoint (change in micturitions/24 hours). The study did find significant differences favoring solifenacin over tolterodine for 3 of 4 secondary efficacy measures. Several comments regarding study design should be noted. In this trial both doses of solifenacin were combined for analysis. Also, the study was designed as a "non-inferiority" trial (i.e. it was not designed to demonstrate superiority).

[1] Madersbacher H, Stohrer M, Richter R, et al. Trospium chloride versus oxybutynin: a randomized, double-blind, multicentre trial in the treatment of detrusor hyper-relexia. Br J Urol. 1995;75(4):452-456.
[2] Halaska M, Ralph G, Wiedemann A, et al. Controlled, double-blind multicentre clinical trial to investigate long-term tolerability and efficacy of trospium chloride in patiuents with detrusor instability. Worl J Urol. 2003;20(6):329-399.
[3] Chapple CR, Martinez-Garcia R, Selvaggi L et al. A comparison of the efficacy and tolerability of solifenacin succinate and extended release tolterodine at treating overactive bladder syndrome: Results of the STAR trial Eur Urol 2005.

Flavoxate, Darifenacin, Scopolamine and Hyoscyamine

No fair or good quality study evaluating the comparative efficacy of flavoxate to oxybutynin or tolterodine was identified. Additionally, in two placebo-controlled trials, flavoxate was not found to be more effective than placebo. Comparative trials of darifenacin, scopolamine, and hyoscyamine were not identified.

Systematic Review

One fair quality systematic review[4] reported efficacy differences between antimuscarinics (oxybutynin, tolterodine, trospium, darifenacin and solifenacin) using clinical outcomes. This review concludes that solifenacin resulted in significantly greater reductions in urgency episodes and micturition frequency when compared to tolterodine IR. However the original study[5] compared the active medications to placebo only and was designed as a "non-inferiority" trial such that claims of superiority are not intended to be drawn from this data. This systematic review also concluded that oxybutynin ER caused a significantly greater mean reduction in incontinenece episodes and a significant increase in the number of patients that returned to continence when compared to tolterodine ER.

1b. In trials of anticholinergic OAB drugs compared to non-drug therapy, other drug therapy, or placebo what is their comparative efficacy?

Placebo-controlled trials of tolteridine (12), oxybutynin (2) and trospium (2) and flavoxate (1) were consistent with head-to-head results except that flavoxate did not find significant differences in efficacy over placebo.

One study comparing solifenacin 5 mg and 10 mg to placebo to assess efficacy demonstrated statistically significant greater reductions in micturitions per 24 hours, number of incontinence episodes, and episodes of urgency for both doses compared to placebo; whereas tolterodine IR was not significantly greater than placebo for urgency and incontinence episodes .[6]

[4] Chapple C, Kullar V, Gabriel Z, et al. The effects of antimuscarinic treatments in overactive bladder: a systematic review and meta-analysis. Eur Urol 2005;48(1):5-26.

[5] Chapple CR, Rechberger T, Al-Skukri S, et al. Randomized, double-blind placebo- and tolterodine-controlled trial of the once-daily antimuscarinic agent solifenacin in patients with symptomatic overactive bladder. BJU Int. 2004;93(3):303-310.

[6] Cardozo L, Lisec M, Millard R, et al. Randomized, double-blind placebo controlled trial of the once daily antimuscarinic agent solifenacin succinate in patients with overactive bladder. J Urol. Nov 2004;172(5 Pt 1):1919-1924..

Three short-term trials (2 to 12 weeks) compared darifenacin to placebo. In the first trial, darifenacin 30 mg was significantly greater than placebo for "warning time" (the time from first sensation of urgency to voluntary micturition or incontinence) but not for mean reduction in micturitions in 24 hours. The second trial comparing darifenacin 7.5 mg to 15 mg and placebo over 12 weeks found significantly greater efficacy for darifenacin in median change in micturitions/24 hours and median change in incontinence episodes/week. Because this trial reported medians and not means, it is difficult to formulate conclusions regarding efficacy. Finally, a 12 week trial comparing darifenacin 3.75mg, 7mg, or 15mg to placebo found significant differences in objective efficacy measures for the 7 and 15 mg doses over placebo, but not the 3.75 mg doses.

Consensus

The Standing Update Committee agrees by consensus that

- *Overall available evidence does not demonstrate consistent differences in objective or subjective efficacy measures among comparisons of oxybutynin IR, oxybutynin ER, oxybutynin TD tolterodine IR, tolterodine ER, trospium and solifenacin.*
- *There is evidence of efficacy for darifenacin and scopolamine only in placebo-controlled trials; therefore no statements about comparative efficacy can be made.*
- *There is no evidence demonstrating the efficacy of flavoxate or hyoscyamine.*

Key Question 2.

For adult patients with urinary urge incontinence/overactive bladder, do anticholinergic incontinence drugs differ in safety or adverse effects?

No long-term head-to-head trial comparing the safety or adverse effects of oxybutynin, tolterodine, or flavoxate were identified. One head-to-head study compared the adverse events in trospium and oxybutynin over 54 weeks. Significant differences were found favoring trospium for adverse events as a whole and for dry mouth. One study compared the discontinuation rates of oxybutynin

and tolterodine via a retrospective prescription claims database. In this study, the proportion of patients discontinuing treatment over a six month period was greater in patients taking oxybutynin; however, discontinuation rates were high among both drugs. Six months after drug initiation, only 32% and 22% of patients on tolterodine and oxybutynin, respectively, continued to refill their prescriptions. In open-label and uncontrolled studies, dry mouth was the most common adverse event. Adverse event rates and withdrawals due to adverse events were similar among drugs evaluated.

Short-term same-drug comparisons of IR and ER formulations reported fewer adverse events rates, particularly dry mouth, with the ER product. One short-term trial of trospium versus oxybutynin IR found a higher incidence of severe dry mouth in Oxybutynin IR (23% vs. 4%) though overall adverse events were comparable.[7] Studies comparing adverse event rates between oxybutynin and tolterodine reported inconsistent results. Overall, the incidence of adverse events, ranging from 49% to 97%, was high for both drugs and the most common adverse event was dry mouth. Two studies did not find significant differences among rates of severe dry mouth between drugs, while one study reported a higher incidence with oxybutynin.

In three studies comparing IR and ER formulations of the same drug, the rates of withdrawals due to adverse events were not significantly different among IR and ER products. Short-term head-to-head comparisons of rates of withdrawals due to adverse events also reported inconsistent results. Two of five studies comparing oxybutynin and tolterodine in any formulation reported statistically significant differences in withdrawal rates among the drugs, both favoring tolterodine. A 54 week trial comparing Oxybutynin IR to Trospium reported overall withdrawal rates of 25% for trospium and 26.7% for Oxybutynin IR; however, withdrawals related to adverse events felt associated with the drugs was higher for oxybutynin (6.7% vs. 3.7%.)[8]

In comparing the extended release formulations, two studies found tolterodine ER to be slightly superior to oxybutynin ER for dry mouth. Comparison of tolterodine ER and oxybutynin TD revealed that dry mouth was more common with tolterodine ER; whereas application site reaction (by necessity) was greater with oxybutynin TD.

Two trials of solifenacin vs. tolterodine showed similar rates of adverse events overall; however, one trial showed lower rates of dry mouth for tolterodine.

[7] *Ibid.*
[8] Halaska M, Ralph G, Wiedermann A, et al. Controlled double-blkind, multicentre cklinical trial to investigate long-term tolerability and efficacy of trospium-chloride in patients with detrusor instability. *World J Urol*. 2003;20(6):392-399

Consensus

The Standing Update Committee agrees by consensus that

- *The overall evidence does not demonstrate consistent differences in adverse events or withdrawals due to adverse events among trospium, solifenacin and IR, ER, or TD forms for oxybutynin and IR or ER forms of tolterodine.*
- *There is insufficient data regarding safety and adverse events for darifenacin.*

Key Question 3.

Are there subgroups of patients based on demographics (age, racial groups, gender and long-term care residents), other medications, or co-morbidities for which one anticholinergic incontinence drug is more effective or associated with fewer adverse effects?

A study on spinal cord injured patients was conducted in multiple centers in Germany. Patients were randomized to a 2 week treatment of Oxybutynin IR 5 mg TID or Trospium 20 mg BID with a placebo at mid-day. The overall rate of side effects including dry mouth was comparable in both groups; however, withdrawal occurred more commonly with Oxybutynin IR (16%) vs. Trospium (3.6%). The study was graded fair because there were demographic and urodynamic parameter differences between the patient groups at baseline. Head-to-head trials evaluating the impact of age, race, gender, or concurrent medications on drug efficacy or safety were not identified. The subcommittee was particularly interested in evaluating the comparative safety and efficacy of drugs in patients living in long-term care facilities (LTC); however, studies meeting inclusion criteria were not identified.

A re-analysis of a subgroup of women from a previous trial showed similar outcomes as the original trial. Another subgroup analysis of women showed that oxybutnin ER may be more effective than tolterodine IR for women <65 years regarding urgency incontinence, total incontinence, and micturation frequency episodes. The incidence of adverse events was similar for both drugs.

Consensus

The Standing Update Committee agrees by consensus that there is insufficient evidence evaluating the effects of subgroup characteristics on the comparative efficacy or safety among incontinence drugs. Conclusions regarding such cannot be drawn.

Conclusion

In a series of public meetings with the opportunity for public questions, comment and testimony, the Standing Update Committee of the Health Resources Commission reviewed the medical evidence comparing Urinary Incontinence drugs in the OHSU EPC's updated final report, which included appropriate information presented in pharmaceutical manufacturer dossiers.

Using all of these sources of information, the update committee arrived at the following conclusions about the comparative effectiveness and safety of urinary incontinence drugs as supported by analysis of the medical literature:

It is the decision of the Standing Update Committee that:

- *Overall, available evidence does not demonstrate consistent differences in objective or subjective efficacy measures especially in the target population to be treated among comparisons of trospium, oxybutynin IR, oxybutynin ER, oxybutynin TD, tolterodine IR, tolterodine ER and solifenacin.*

- *There is evidence of efficacy for darifenacin and scolpolamine only in placebo-controlled trials; therefore, no statements about comparative efficacy can be made*

- *There is no available evidence demonstrating the effectiveness of flavoxate or hyosycamine.*

- *Overall evidence does not demonstrate consistent differences in adverse events or withdrawals due to adverse events especially in the target population to be treated among trospium, solifenacin, and IR, ER, or TD forms for oxybutynin and IR or ER forms of tolterodine. All the OAB drugs as a class have a high incidence of side effects.*

- *There is insufficient evidence evaluating the effects of subgroup characteristics on the comparative efficacy or safety among incontinence drugs. Conclusions regarding such cannot not be drawn.*

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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 the 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 meetings and public testimony in developing its final reports.