

29 September 2006

Executive Summary

UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL COMMENTS September 2006

The Uniform Formulary Beneficiary Advisory Panel commented on the recommendations from the DOD Pharmacy & Therapeutics Committee August 2006 meeting.

1. Antilipidemic (LIP-1) drug class: The P&T Committee recommended that atorvastatin (Lipitor), fluvastatin immediate and extended release (Lescol, Lescol XL), pravastatin (Pravachol, generics), simvastatin (Zocor, generics), lovastatin immediate and extended release (Mevacor, generics; Altoprev), lovastatin/niacin (Advicor), ezetimibe/simvastatin (Vytorin), niacin immediate and extended release (Niacor, Niaspan), and ezetimibe (Zetia) be maintained as formulary on the UF and that rosuvastatin (Crestor) and atorvastatin/amlodipine (Caduet) be classified as non-formulary. The P&T Committee recommended an effective date no earlier than the first Wednesday following a 90-day implementation period. The implementation period will begin immediately following approval by the Director, TMA.

Summary of Panel Vote/Comments:

The Beneficiary Advisory Panel voted unanimously (10-0) to concur with the P&T Committee's recommendation for non-formulary status. In regards to the implementation period, the Panel vote was: 8 concur and 2 non-concur.

- Panel members stated that they believe that if DOD had a system in place to notify beneficiaries personally when their medications change status within the UF, the implementation period could be shorter. The Panel requested that Dr. Winkenwerder consider such a notification system.

Director, TMA: BW

- These comments were taken under consideration prior to my final decision.

2. Thiazolidinedione (TZD): The P&T Committee recommended that the UF scenario that maintained rosiglitazone (Avandia), pioglitazone (Actos), rosiglitazone/metformin (Avandamet), pioglitazone/metformin (Actoplus Met), and rosiglitazone/glimepiride (Avandaryl) on the UF formulary was the most cost effective UF scenario considered.

Summary of Panel Vote/Comments:

- The Panel voted to concur unanimously (11-0) with the recommendation.

Director, TMA: BW

- These comments were taken under consideration prior to my final decision.

3. Histamine-2 (H2) Antagonists and Other Gastrointestinal (GI) Protectants: The P&T Committee recommended that the H2 antagonists ranitidine (Zantac, generics), cimetidine (Tagamet, generics), famotidine (Pepcid, generics) and nizatidine (Axid, generics); the prostaglandin analog misoprostol (Cytotec, generics); and the mucosal protective agent sucralfate (Carafate, generics) should be maintained on the UF and that no agents from this class be classified as non-formulary.

Summary of Panel Vote/Comments:

- The Panel voted to concur unanimously (11-0) with the recommendation.

Director, TMA: BW

- These comments were taken under consideration prior to my final decision.

4. Prior Authorization for Byetta: The committee agreed that the following PA criteria should apply. Patients meeting the automated PA criteria would not be required to have their providers submit any additional information and in all likelihood would not even be aware of the existence of the PA. PA approvals would be valid indefinitely.

1) Automated PA criterion:

- Patient has received any oral antidiabetic agent in the last 120 days.

2) PA criteria if automated criterion is not met:

- Coverage is approved if the patient meets both of the following criteria:
 - Diagnosis of type 2 diabetes mellitus (DM)
 - Patient has not achieved adequate glycemic control on metformin, a sulfonylurea, or a combination of metformin and a sulfonylurea.

Summary of Panel Vote/Comments:

- The Panel voted to concur unanimously (11-0) with the recommendation.

Director, TMA: BW

- These comments were taken under consideration prior to my final decision.

Uniform Formulary Beneficiary Advisory Panel

Meeting Summary
September 21, 2006
Washington, D.C.

Panel Members Present:

- John Class, Military Coalition, Chairman
- Kathryn Buchta, TRICARE Network Provider
- Deborah Fryar, Military Coalition
- Marshall Hanson, National Military and Veterans Alliance
- Sydney Hickey, Military Coalition
- Rance Hutchings, Uniformed Services Family Health Plan
- Lisa Le Gette, TRICARE Retail and Mail-Order Pharmacy Contracts
- Jeffrey Lenow, Medical Professional
- Jan Prasad, TRICARE Network Provider
- Charles Partridge, National Military and Veterans Alliance
- Marissa Schlaifer, Medical Professional

The meeting was held at the Naval Heritage Center Theater, 701 Pennsylvania Ave., N.W., Washington, D.C. Major (MAJ) Travis Watson, the Designated Federal Officer (DFO), called the proceedings to order at 8:00 a.m.

MAJ Watson indicated this meeting of the Panel has been convened to discuss and review the recommendations of the Department of Defense (DOD) Pharmacy and Therapeutic (P&T) Committee meeting held on August 15-17, 2006 in San Antonio, TX.

Agenda

The agenda for the June meeting of the Panel is:

- Opening remarks and public comments
- Consideration of antilipidemic (LIP-1) drug class recommendations
- Consideration of thiazolidinedione (TZD) drug class recommendations
- Consideration of histamine-2 (H2) antagonist and other gastrointestinal (GI) protectants drug class recommendations
- Consideration of Byetta prior authorization (PA) recommendations
- Wrap-up comments

Opening Remarks

MAJ Watson stated that under 10 United States Code (U.S.C.) section 1074g the Secretary of Defense is required to establish a DOD Pharmacy and Therapeutics (P&T) Committee for the purpose of establishing a Uniform Formulary (UF) of pharmaceutical agents, review the formulary on a periodic basis and make additional recommendations regarding the formulary as the Committee deems necessary and appropriate.

10 U.S.C. section 1074g also requires the Secretary to establish a Uniform Formulary Beneficiary Advisory Panel (BAP) to review and comment on the development of the Uniform Formulary. The Panel shall include members that represent non-governmental organizations and associations that represent the views and interests of a large number of eligible covered beneficiaries. Comments from the Panel must be considered before implementing changes to the Uniform Formulary. The Panel's meetings are conducted in accordance with the Federal Advisory Committee Act (FACA).

The duties of the Uniform Formulary Beneficiary Advisory Panel are:

- To review and comment on the recommendations of the P&T Committee concerning the establishment of the Uniform Formulary and subsequent recommended changes. Comments to the Director, TRICARE Management Activity (TMA), regarding recommended formulary status, pre-authorizations, and suggested dates for changing from "formulary" to "non-formulary" status must be reviewed by the Director before making a final decision.
- To hold meetings in an open forum quarterly. The Panel may not hold meetings except at the call of or with the advance approval of the Chairman of the Panel.
- To prepare minutes of the proceedings and prepare comments for the Secretary or his designee regarding the Uniform Formulary or changes to the Formulary. The minutes will be available on the website and comments will be prepared for Dr. Winkenwerder.

As guidance regarding this meeting, MAJ Watson said the role of the Beneficiary Advisory Panel is to comment on the Uniform Formulary recommendations made by the P&T Committee at their last meeting, August 15-17, 2006. While the Department appreciates that the BAP may be interested in the drug classes selected for review, drugs recommended for the basic core formulary (BCF) or specific pricing data, these topics do not fall under the purview of the BAP.

The P&T Committee met for approximately 20 hours to consider the class review recommendations presented today. Since this meeting is considerably shorter, the Panel will not receive the same extensive information that is presented to the P&T Committee members. However, the BAP will receive an abbreviated version of each presentation and its discussion.

Detailed minutes of this meeting are being prepared. The BAP minutes, the DOD P&T Committee meeting minutes and Dr. Winkenwerder's decisions will be available on the TRICARE website in approximately four weeks.

MAJ Watson next reviewed the ground rules for conducting the meeting:

- All discussion takes place in the open public forum. There is to be no committee discussion outside the room, during breaks or at lunch.
- Audience participation is limited to private citizens who signed up to address the Panel.
- Members of the Pharmacoeconomic Center (PEC) and the P&T Committee are available to answer questions related to the BAP's deliberations. Should a misstatement be made, these individuals may interrupt to ensure that the minutes accurately reflect relevant facts, regulations or policy.

MAJ Watson introduced the members of the Beneficiary Advisory Panel present, including a new member, Kathryn Buchta of Health Net Federal Services (replacing Dr. Miller). He also introduced individuals in the audience who might be participating in the session.

MAJ Watson then briefly reviewed housekeeping considerations.

Private Citizen Comments

MAJ Watson opened the meeting for private citizen comments. There was no response.

Opening Remarks by the Chair

The Panel Chairman, Mr. John Class, noted that the Panel received a briefing in March on the results of the reviews so far and reminded the staff that the Panel is still looking for data on actual savings. MAJ Watson said that the requested information is being prepared – the staff is updating the same information for Dr. Winkenwerder and is planning to synchronize the two presentations.

Presentation on Antilipidemic (LIP-1) Drug Class Review

Clinical Effectiveness Review

Major (Maj) Wade Tiller, Deputy Director of the Pharmacoeconomic Center (PEC), opened the presentation by introducing the presenting staff: Lieutenant Colonel (Lt Col) Jim McCrary, Dr. Harsha Mistry and Dr. Julie Liss, all of the PEC Clinical Operations Staff, and Commander (CDR) Michelle Perello, a member of the P&T Committee, who will provide the Panel with the physician's perspective.

[Insert script, pages 1 through 11]

Cost Effectiveness Review, Antilipidemic (LIP-1) Drug Class, and Recommendations

Maj Tiller presented the cost effectiveness review and P&T Committee recommendations for the LIP-1 drug class.

[Insert script, pages 12 through 14]

Physician Perspective

CDR Perello discussed the physician's perspective, commenting that the briefers had done a very good job of presenting the pros and cons of the medications from a clinical perspective. In regard to Crestor, she said there were some indications that warrant further monitoring but acknowledged that there may be some patients who actually need it.

Dr. Lenow asked for clarification about including Vytorin being in the statin drug class. He said it is not a statin *per se*, even though it is included in the class as a term of art. He also noted that amlodipine, classified as non-formulary earlier, is included along with atorvastatin in the

combination drug Caduet. He said the presentation sounded like the cost to the government would be higher if the drug was kept on formulary. He questioned what the overall cost effect would be for the end user, who is on a calcium channel blocker, of having to have scripts written separately for the generic equivalent of amlodipine and atorvastatin compared to the cost of a single script for Caduet.

Maj Tiller said the PEC recognizes that Vytorin is not a statin, but decided to include it in that sub-class for purposes of Uniform Formulary evaluation so it would be compared along with intensive-dose statins. Regarding the cost of separate scripts, Maj Tiller replied that both Zocor and a generic calcium channel blocker are available in generic form. If a patient elected to have two prescriptions filled instead of one, the total co-pay would be \$6.00 (versus \$9.00 for the brand product co-pay of the combination drug if it were on formulary).

Dr. Lenow observed that the trade-off, in that case, would be compliance. He cited an earlier study showing that only about one-third of the patients who need to be on these drugs are actually on them, and only half of that group are at goal. Compliance is a big issue for him. With the higher impact statins, not only are patients not reaching goal, but the guidelines have been adjusted, making physicians more aggressive in their low-density lipoprotein (LDL) goals, especially with diabetics. Anything that can intensify the impact of LDL-lowering has to be taken very seriously. His concern about Crestor being non-formulary is that it does have high impact potential.

CDR Perello pointed out that Crestor will still be available for the very small part of the Military Health System (MHS) population that really needs it.

Dr. Prasad said that, as a practicing cardiologist, his experience is that you can count the number of patients using Crestor on one hand. Physicians can do anything with Zocor and Vytorin that they can do with Crestor. He isn't concerned about having Crestor classified as non-formulary.

Panel Discussion of Antilipidemic (LIP-1) Drug Class Recommendations

Mr. Class opened the subject for general discussion among the Panel.

Dr. Hutchings pointed out that today's agenda doesn't call for moving a lot of drugs to the third tier. He observed that the discussion of Crestor had centered on the drug in a 40 mg dosage, but that Crestor in lower doses had turned out to be cost-effective. He asked if there had been any discussion of restricting only Crestor-40 and not other formulations. He also said that a comment had been made that when the 6-month exclusivity for Zocor expires there will be other statins in that class that should be looked at. Noting that this is the most expensive class of drugs – involving many millions of dollars – he asked whether consideration was being given to moving other drugs to third tier in a few months. He asked for clarification of why so few drugs are being classified as non-formulary and why Crestor was being classified as non-formulary in all its formulations.

Maj Tiller said the Committee had looked at splitting out the decision on Crestor by doses. The evaluation showed that this approach would not be a good alternative. As to why the recommendations were not more restrictive, Maj Tiller said that the P&T Committee looked at the class in May to construct a conceptual approach for how to evaluate that class. The Committee was very adamant about having at least one high-intensity LDL-lowering agent

available on the Uniform Formulary. That meant that Zocor plus at least one other agent would have to be on the Uniform Formulary. When bids were submitted by manufacturers, the PEC chose a scenario that provided the greatest economic benefit for the MHS. Many different types of scenarios were considered, but the one recommended provided the greatest benefit. A large number of people do not get their prescriptions filled at the military treatment facility (MTF), but at retail and mail order. The PEC has demonstrated the ability to move market share at the MTF, but it doesn't have the same ability at the other points of service (although it is able to move some market share). Because of that, making other drugs non-formulary at the other two points of service is not always cost-beneficial to the MHS.

Captain (CAPT) Richerson said that PEC is very sensitive to the issue. The MHS objective, and that of other health plans, is to optimize the use of simvastatin (Zocor) where it is clinically focused. He said there are utilization thresholds for the use of simvastatin and that PEC will be watching like a hawk. The recommendation provides unfettered access to a broad array of products in the class. If physicians need the high-intensity agent they will be able to get to it without a lot of hurdles. If the utilization of simvastatin crosses over the threshold, the Committee could very easily go back and re-look at this class and adopt utilization management tools. But in this case it was judged to be not necessary at this time.

Mr. Hanson suggested that moving Crestor to non-formulary was an action that would not really bring about much cost saving. Rather, it seems to be some sort of exercise. His view is that tracking patients who really need Crestor will show that they will be getting the medical necessity exemption anyway. He believes what's going to happen is that MHS will still be prescribing it under medical necessity and there won't be any cost savings. He said that is something to track and be aware of.

Maj Tiller replied that the MHS experience to date has been that the majority of people on a non-formulary drug who elect not to move to a formulary drug simply pay the \$22 co-pay and don't seek a medical necessity. Very few people use the medical necessity process, even though it reduces the cost to a \$9 co-pay.

Ms. Le Gette agreed with Maj Tiller, saying that what he described is exactly what her organization is seeing. It's probably because of the co-pay differential – other plans have co-pay requirements that range from \$45 to \$75.

Mr. Hanson said that it also indicates a need for the associations to do a better job of educating people about what their options are. If the beneficiary feels it's a medical necessity and the doctor confirms it, they should be taking advantage of it rather than paying the higher cost.

Ms. Hickey said the associations also need to do a better job of educating beneficiaries on the mail order pharmacy because there isn't any automatic way for beneficiaries who are using retail to understand that they are going to save money with the mail order. A lot of people don't use it because they just don't know about it. She also disagreed that people *choose* not to use the MTF for their pharmacy. A great many beneficiaries are unable to use MTFs because they can't get an appointment to get a prescription so they can use the MTF. Mr. Hanson added that they may also reside a long distance away from an MTF, making other sources more economical, even though they would love to use it.

Ms. Le Gette asked about the current PA requirement for certain statins. She asked if that would terminate when the implementation date is set for this class. The answer was affirmative. She also asked about Zocor, which has been termed the "workhorse statin." She asked if the PEC now thinks that market share for a product like Lipitor will increase at the MTF. Maj Tiller acknowledged that it is a concern, as CAPT Richerson had said earlier, and the PEC will monitor the situation very closely.

Dr. Prasad asked for clarification about the cost difference between Lipitor and Crestor. Maj Tiller answered that both were considered to have the same relative cost-effectiveness. He said three of the four models used the intermediate outcome measure of LDL or total cholesterol to high-density lipoprotein (HDL) ratio. Given Crestor's ability to lower cholesterol more than Lipitor, it was slightly more effective, and it was competitively priced. But when you look at the big picture, they both had similar relative cost-effectiveness. The "big picture" includes other considerations, such as the budget impact analysis, the scenario with Lipitor on formulary and Crestor not on formulary was more favorable for the MHS overall. CDR Perello added that from a clinical standpoint there also was a preference for Lipitor over Crestor. If the clinical data had favored Crestor over Lipitor, the Committee would have gone with Crestor, but that wasn't the case.

Dr. Hutchings asked for a clarification on the significance of the February 1 date included in the recommendation. If the Panel was to recommend that the implementation period should be six months, he asked if that would put DOD in a pickle. The answer is that the February 1 date results from a contractual agreement reached between DOD and the supplier, so anything beyond that would cause difficulties.

Ms. Fryar asked for clarification about the implementation plan statement that MTFs may fill prescriptions for patients who have been referred to non-MTF providers as long as medical necessity has been established. Specifically, she asked about patients who are going to non-MTF providers under TRICARE standard, if they are eligible to have the prescription filled at the MTF. The answer was that they are not.

Panel Vote on Antilipidemic (LIP-1) Drug Class Formulary Recommendations

Mr. Class next called for a panel vote on the formulary recommendation for this drug class:

"Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Antilipidemic 1 agents, and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted to recommend that atorvastatin (Lipitor), fluvastatin immediate and extended release (Lescol, Lescol XL), pravastatin (Pravachol, generics), simvastatin (Zocor, generics), lovastatin immediate and extended release (Mevacor, generics; Altoprev), lovastatin/niacin (Advicor), ezetimibe/simvastatin (Vytorin), niacin immediate and extended release (Niacor, Niaspan), and ezetimibe (Zetia) be maintained as formulary on the UF and that rosuvastatin (Crestor) and atorvastatin/amlodipine (Caduet) be classified as non-formulary."

The Panel voted unanimously (10-0) to concur with the P&T Committee's recommendation.

Panel Discussion of Implementation Plan Recommendations for the Antilipidemic (LIP-1) Drug Class

Ms. Schlaifer asked about the need to make the change sooner rather than later. Specifically she asked whether the two drugs are married as far as the implementation date is concerned. With the statin alone, if the formulary misses compliance by a couple of days there won't be a big problem. But with the amlodipine combination, it might be more of an issue if someone misses a couple of days' doses. The question is whether the implementation of both must be handled on one date or can they be split. MAJ Watson replied that there must be one implementation date.

Mr. Class read into the record an e-mail received from a beneficiary regarding implementation notification:

“Chairperson, Uniform Formulary Beneficiary Advisory Panel:

I am very concerned that there is no process for notification of individuals who are already taking a particular maintenance medication that had been on the formulary, when that medication is deleted.

I had been on a medication for a period of time that was removed from the formulary several months ago. I found out only by chance when I called Express Scripts on another issue while transitioning the rest of my medications to TMOP, and heard on the opening menu message that it had been deleted. I received no notification and would have had a very rude awakening had I ordered a refill and then had to pay \$22.00 rather than the \$9.00.

I have used the formulary site to check new medications, but had been taking the particular medication for over a year. Until recently, I was not aware of the availability of the information-specific TMA mailing list subscriptions, but have subsequently subscribed to receive the press releases pertaining to formulary changes. I had gotten TRICARE information emails in the past (none recently), but if I recall correctly, they were about reporting fraud and such. There had not been any information relating to formulary changes.

That said, how does an individual, especially our elderly, non-computer literate veterans get this vital information?

I do not believe that it is proper to put an individual in the position of ordering medication refills, then having that "rude awakening" I mentioned with a co-pay of \$22.00 rather than \$9.00. This is especially the case, with those elderly individuals who are in no position to be able to absorb even that (to most of us) relatively small increase in cost. Anyone who does not have access to a computer and has no need to call Express Scripts is in that very position.

I request discussion and consideration of a process by which beneficiaries are notified when changes to the formulary impact the medications which they are taking.

Thank you in advance for your reply.”

[Name redacted]

Mr. Class reiterated a concern related to the above that the Panel has voiced all along – that notification relies on the associations. Unless people are internet-savvy, they don't find out about changes until they get to the point of delivery. For their publications, the associations generally need a good three or four months from the time a decision is made to get the notice out. He said this e-mail is very typical of what the associations hear from their members.

Panel Vote on Implementation Plan Recommendation for the Antilipidemic (LIP-1) Drug Class

Mr. Class read the P&T Committee recommendation:

“The P&T Committee recommended an effective date no later than the first Wednesday following a 90-day implementation period. The implementation period will begin immediately following the approval by the Director, TMA.”

The Panel vote was: 8 concur and 2 non-concur.

Mr. Hanson commented that, while he supports the recommendation, he hopes that in reviewing it TMA will take it out to the maximum time frame, which will be close to the February 1, 2007 date to allow the word to get out to the beneficiaries.

Mr. Class said the way he hears that comment is that Mr. Hanson basically does not concur with the recommendation. Mr. Hanson clarified by noting that because of adherence to contract limitations (the February 1, 2007 date), some members of the Panel feel that their hands are tied.

Dr. Hutchings said that the difference is only about a week.

Mr. Class said he, as a Panel member, isn't concerned with DOD contract dates. That shouldn't enter into the Panel's consideration. The question is: “What does the Panel think the implementation time frame should be?” In other words, whether everybody agrees with the 90-day implementation period. The statement that the time frame should be pushed out as far as possible suggests that there is disagreement with the 90-day implementation period.

Mr. Class referred back to the discussion at the June meeting of the Panel, at which the instruction was for the Panel to deal with the recommendations submitted by the Committee. If the Panel feels more time is necessary, it should non-concur with the recommendation and provide comments.

Dr. Hutchings said his reading of the recommendation was that the plan was for implementation in “90 days, no later than February 1.” That was the recommendation that was stated from the podium.

Maj Tiller clarified that the recommendation is for “no sooner than 90 days, no later than 1 February, 2007.”

Mr. Class questioned the “no later than February 1” clause, pointing out that the material received says something different. He said he doesn't understand the clause. Heretofore, the

recommendations have always been for a set number of days from approval of the recommendation.

A P&T staff member clarified that the Committee voted, at the meeting itself, for implementation in "no earlier than 90 days." They were aware that the current statin contract entered into by DOD had not been resolved with Merck as far as a clean exit strategy, so the Committee said "no earlier than." Discussions with Merck over the last couple of weeks have agreed to formally terminate the contract February 1, 2007. It is a joint contract with the Veterans' Affairs (VA) and all parties have agreed to that time. So the additional date of February 1 reflects the contract resolution.

Ms. Hickey commented that this discussion again brings up the subject that has been discussed at every meeting of the Panel so far. There has to be a process for notifying beneficiaries. When beneficiaries are notified of the changes and their implementation dates, concern over the implementation dates will begin to wane because beneficiaries will have enough time to make reasonable decisions. Right now, the beneficiaries' time frame is normally when they send in their renewal to Express Scripts or refill their prescription at the retail pharmacy. That's hardly enough time to make a decision on what you want to do. A review of the comments made on implementation over the months that the Panel has been in existence will show that has consistently been the problem – beneficiaries were not provided notification in enough time.

Mr. Hanson commented that the question also brings up another issue the Panel has raised in the past – the voting structure itself. One of the Panel members raised the issue of having two drugs voted into non-formulary status on the same timetable. An option could have been included to put the agents on different timetables. In the past people have also voted for the positive or the negative because of the inclusion or exclusion of a drug presented to the Panel. The voting system is inflexible and can result in people voting in ways opposite to how they want to vote. He said in this case many Panel members would like to vote for a longer implementation period but feel they don't have any choice but to support DOD at this time.

MAJ Watson commented that he thinks the Chairman's approach is the correct one. The judgment of the Panel is what it is, up to 180 days. That judgment should be put in the record as a comment.

Mr. Class said what he has on his sheet is the official recommendation of the P&T Committee. What he is hearing now is that it is not the "official recommendation." If the P&T has a different published recommendation, that's what the Panel needs to vote on.

Mr. Lynn Bursleson, TMA General Counsel's office, affirmed that Mr. Class' position is the correct one, i.e. the Panel is to vote on the official P&T recommendation that came out of the meeting.

Mr. Class acknowledged that there is a contract issue, but that the Panel needs to vote on the 90-day recommendation. Ms. Hickey said she thinks the Panel should re-vote because it was taking into account the February 1 deadline before.

Dr. Buchta asked whether the Panel has any authority to change processes for notifying beneficiaries. Mr. Class answered in the negative. Dr. Buchta then asked whether the implementation date should be "held hostage" for notification of beneficiaries, which seems to

be the main issue. Mr. Class replied that the only authority the group has is to non-concur with the recommendation (the implementation date in this case). A year and a half ago when the Panel first met it raised the issue of DOD having no notification process. Dr. Buchta asked what would be gained by extending the implementation date to 120 or 180 days. Mr. Class replied that it would give the associations a chance to get notification into its magazines and get the information about changes in the formulary out to members. If DOD made a separate notification directly to beneficiaries there would be no issue. Dr. Buchta asked how many of the applicable beneficiaries are reached by the association publications. Mr. Class said his organization's magazine reaches 370,000 people, but that isn't the issue. The issue is that there is no DOD notification to the beneficiaries.

Ms. Fryar commented that she doesn't believe it should be the responsibility of the associations to get the information out to the beneficiaries. That should be a TRICARE job.

Ms. Hickey added that, from the beginning, when the Panel has raised questions on implementation dates and has recommended changes on several, almost all have been based on the issue of beneficiary notification. The Panel has felt that it was correct and fair to inform Dr. Winkenwerder that its decision was not necessarily made on a clinical basis, but on the basis that patients needed to have a little bit more lead time in order to make informed decisions.

Mr. Hanson noted that the Panel's name is the "Beneficiary Advisory Panel." Technically, it cannot "hold hostage." It doesn't have that authority; it simply advises the Secretary, who has the authority and makes the decisions.

MAJ Watson made an official correction to the P&T Committee recommendation as written. Where the effective date says "no *later* than" the wording should read "no *earlier* than." The remainder of the recommendation is correct.

Mr. Class said that is too ambiguous a recommendation. MAJ Watson said it reflects the uncertainty about how the current contract issue was going to be resolved. All they knew at the time of the meeting was that it would be no earlier than 90 days.

Re-Vote on Implementation Plan Recommendation

Mr. Class read the P&T Committee's corrected recommendation:

"The P&T Committee recommended an effective date no earlier than the first Wednesday following a 90 day implementation period. The implementation period will begin immediately following approval by the Director, TMA."

The Panel vote was: concur 6 and non-concur 4.

Note: Mr. Partridge arrived late and did not vote on this drug class.

Comments on Panel Vote

Ms. Fryar commented that she is concerned that the issue is tied to a contract. The Panel is making recommendations for the beneficiaries in regard to the implementation plan. The Panel vote reflects the standardized approach that it has taken to date. If it knew that formal

notification of beneficiaries was in place, the Panel would be much more likely to support the recommended implementation time frames.

Mr. Class agreed with the comment, stating that if DOD had a notification process there would be fewer “non-concur” votes.

Dr. Buchta asked whether the Panel could make a recommendation to Dr. Winkenwerder to consider directing his management activity to address the notification process or lack thereof. Mr. Class agreed that the Panel could do so again.

As an aside, Dr. Hutchings asked whether there is any reason why data can't be pulled from the Pharmacy Data Transaction Service (PDTS) to create mailings. That would allow notification to be sent out very quickly – three days – informing people about what their options are no matter how many patients are involved.

Presentation on Thiazolidinedione (TZD) Drug Class Review

Clinical Effectiveness Review

Maj Tiller introduced Dr. Julie Liss and Lt Col McCrary to present the clinical effectiveness review for the Thiazolidinedione (TZD) Drug Class.

[Insert script, pages 15-21]

Cost Effectiveness Review of the (TZD) Drug Class and Recommendations

Next, Maj Tiller presented the cost effectiveness review and P&T Committee recommendations for this drug class.

[Insert script, pages 22 and 23]

Physician Perspective

CDR Perello provided the Panel with the physician's perspective on the P&T Committee's review and recommendations in this drug class. She said she didn't have anything to add to the presentation but would be happy to answer clinical questions.

Mr. Partridge asked whether CDR Perello had actually prescribed drugs in this class and, if so, whether she had a favorite. CDR Perello said she had prescribed drugs in this class and did not have a favorite. She said she didn't think physician preference would be a big issue. Most diabetics are on statins anyway, so the approach is going to be to try one and see how the patient does. If there is a drug interaction, the physician will switch to the other available agent.

Panel Questions and Discussion

Ms. Hickey questioned Maj Tiller about the two P&T Committee votes to abstain. She noted that this is somewhat unusual. Maj Tiller confirmed the Committee vote on the recommendation.

Mr. Hanson commented that the presenters had done an excellent job and that he appreciated the fact that the presentation moved quickly. He also noted that the recommendation in this case was not to move any agents to non-formulary. He asked whether such cases in the future might be summarized even more briefly. He pointed out that the only action available to the Panel would be to not accept the recommendation, which would mean that someone on the Panel believes there is a drug within the category that should be classified as non-formulary. Most of the Panel members do not have the expertise to make such a recommendation. Those who do would still be free to bring in their questions and get into the details. But if no one on the Panel has any disagreement with the recommendations, the review and discussion process should be very quick as the subject matter would be non-controversial.

MAJ Watson replied that there is no reason that can't be done. He said he would discuss it with the Chair for future classes.

Dr. Hutchings, while agreeing, noted that it is useful to have the background information. He likes the "read ahead" material in its present form. Mr. Hanson agreed, noting that it would provide the basis for questions.

Panel Vote on Thiazolidinedione (TZD) Drug Class Recommendations

Mr. Class read the recommendation:

"The P&T Committee, based upon its collective professional judgment, voted to accept the TZD cost analysis presented by the PEC. The P&T Committee concluded that the UF scenario that maintained rosiglitazone (Avandia), pioglitazone (Actos), rosiglitazone/metformin (Avandamet), pioglitazone/metformin (Actoplus Met), and rosiglitazone/glimepiride (Avandaryl) on the UF formulary was the most cost effective UF scenario considered."

The Panel voted unanimously (11-0) to concur with the recommendation.

Presentation on Histamine-2 (H2) Antagonists and Other Gastrointestinal (GI) Protectants Drug Class Review

Clinical Effectiveness Review

Maj Tiller introduced Dr. Harsha Mistry to present the H2 antagonists and other GI protectants' clinical effectiveness review.

[Insert script, pages 24 through 27]

Cost Effectiveness Review and P&T Committee Recommendations

Maj Tiller presented the cost effectiveness review results and the P&T Committee recommendations for this drug class.

[Insert script, page 28]

Physician Perspective

CDR Perello answered the Panel's clinical questions.

Dr. Lenow commented that the use of cimetidine is very low. He noted that there was a time when the community was discussing cimetidine's potential side effect of disorientation on the elderly. He said he has seen it personally. The effect may have been caused by a free radical in the structure of cimetidine that is somewhat similar to LSD. He said there are so many choices available in this drug class that if he was voting on cimetidine he would vote to keep it on formulary only for its other uses.

CDR Perello said there are people in the community who do use it for other uses, such as allergy.

Panel Discussion and Vote on Histamine-2 (H2) Antagonists and Other Gastrointestinal (GI) Protectants Drug Class

There was no Panel discussion of the recommendation in this drug class.

Mr. Class read the P&T Committee recommendation:

"Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the H2 antagonists & other GI protectants, and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted to recommend that the H2 antagonists ranitidine (Zantac, generics), cimetidine (Tagamet, generics), famotidine (Pepcid, generics) and nizatidine (Axiid, generics); the prostaglandin analog misoprostol (Cytotec, generics); and the mucosal protective agent sucralfate (Carafate, generics) should be maintained on the UF and that no agents from this class be classified as non-formulary."

The Panel voted unanimously (11-0) to concur with the recommendation.

Presentation on Prior Authorization Requirements for Byetta

Maj Tiller introduced Dr. Liss to present the prior authorization (PA) requirements for Byetta.

[Insert script, pages 29 & 30]

Panel Questions and Discussion of the Byetta PA

Ms. Le Gette asked if it is the case that the PA will not be implemented until the automated system is ready to go. The answer is that MHS is anticipating that PDTS will provide a PA capability in many areas. Ms. Le Gette asked if the intent is to have all of the current users of Byetta obtain a PA or will they be grandfathered. The answer was that all would have to have a PA.

Dr. Lenow noted that the PA would require evidence that a patient had failed on metformin or a sulfonylurea, but the criteria do not list TZD. He asked why. The answer was that the Food and Drug Administration (FDA) approved the use of Byetta with TZDs. Dr. Lenow observed that

the concern here is that, lacking the evidence required for the PA, the assumption is that Byetta is being used for the wrong reason – weight loss, primarily. He asked if that is being done for other situations, such as Topamax. Maj Tiller answered that other situations are being evaluated on a case-by-case basis. He said he has seen the *Wall Street Journal* article about Topamax being used for weight loss, but Topamax hasn't yet appeared on the PEC's radar. If there is evidence that it is becoming a problem, the P&T would address it. Dr. Lenow also noted that Topamax has a higher unit cost that would make it more of a "red flag" than some others. Maj Tiller added that the PEC looked at Byetta not long ago as a new drug and recognized then that it would need to be monitored because of its potential for weight loss.

Dr. Lenow commented that the philosophy behind the new approach to diabetes relies on oral agents that may make the Byetta discussion moot. He said there is a pipeline of 6 or 7 new agents ready to be approved. Dr. Liss said it is still too early to tell how the new agents will fit in with the treatment programs.

Dr. Hutchings asked if the automated program would reject Byetta for patients who are on insulin now. The answer provided was that it is currently being studied, but insulin is not currently a supplement. Dr. Lenow added that the theory is that it would offset the use of insulin. Dr. Hutchings said his concern is whether the PDTS would have the capability to reject a PA based on a red flag should a conflict pop up.

Ms. Schlaifer asked what happens at the community pharmacy level. Does the system send a message back that tells them to let the patient know they need a prior authorization? The answer was that it does.

Ms. Fryar asked about the 10 percent of patients that are currently using Byetta who would not meet the automated criteria – how many would seek to continue treatment and whether they would be grandfathered in. The answer provided was that MHS doesn't know how many patients will actually want to be continued when a PA is required. They are anticipating that only a small number of patients will be affected by the decision.

Panel Vote on the Byetta PA Recommendation

Mr. Class read the implementation plan recommendation:

"The Committee recommends that the PA should have an effective date no sooner than the first Wednesday following a 30-day implementation period, but as soon thereafter as possible based on availability of the automated PA capability in PDTS. The implementation period will begin immediately following the approval by the Director, TMA."

Discussion

Ms. Hickey commented that the recommendation says two different things. One is that Dr. Winkenwerder has to approve it before the process starts. The other is that the PDTS has to be up and running. She asked which condition is germane.

The answer was that the implementation will be no sooner than 30 days, but it could be later, depending on the availability of the PDTS.

Ms. Hickey said she isn't sure that both conditions should be in the recommendation. Dr. Buchta commented that she agrees that the automated system should be in place first.

Ms. Hickey said the recommendation could be fixed by saying that "the implementation period will begin immediately following the approval by the Director and the recognized capability of PDTS." She said she is a little skeptical about how fast the PDTS is going to be operational.

The Panel voted unanimously to concur with the recommendation.

The Panel included a comment that implementation should begin immediately following operational PDTS implementation and approval by the Director, TMA.

Panel Vote on PA Criteria

Mr. Class read the P&T Committee recommendation:

"The committee agreed that the following PA criteria should apply. Patients meeting the automated PA criteria would not be required to have their providers submit any additional information and in all likelihood would not even be aware of the existence of the PA. PA approvals would be valid indefinitely.

1) Automated PA criterion:

- Patient has received any oral antidiabetic agent in the last 120 days.

2) PA criteria if automated criterion is not met:

- Coverage is approved if the patient meets both of the following criteria:
 - Diagnosis of type 2 diabetes mellitus (DM)
 - Patient has not achieved adequate glycemic control on metformin, a sulfonylurea, or a combination of metformin and a sulfonylurea."

Dr. Hutchings asked about the PA being "indefinite" and whether a patient who has a PA for a drug that goes generic would still allow them to obtain the brand drug. The answer was that the PA would be superseded and people will not be grandfathered into branded products.

The Panel voted unanimously (11-0) to concur with the recommendation.

Closing Remarks

MAJ Watson announced that the next meeting will be December 20 at 8:00 a.m. at the Naval Heritage Center in Washington, D.C. Formal announcement will be posted in the *Federal Register*.

Dr. Hutchings commented that it looks like the process is starting to combine a lot of classes. This sometimes confuses matters when the Panel votes. For example, he sees GI protectants and H2 blockers as two completely different beasts. Also niacin and statins. He asked if there is any way that the Panel could vote separately in such cases. He is uncomfortable being asked to vote on one set of combined recommendations.

The General Counsel answered that the Panel must vote on the recommendation that comes out of the P&T Committee. But it can make comments that differentiate sub-classes.

Mr. Class asked whether the Panel could make a recommendation that the P&T Committee should review how it structures its recommendations. Mr. Burleson agreed that would be appropriate.

CAPT Richerson said that a lot of consideration goes into how the P&T Committee decides what constitutes a particular drug class. The matter of where to classify a particular drug is a problem that will occur over and over again. From a therapeutic standpoint, it's hard to say where a lot of these drugs should be classified. It may not be practical to restructure the review and analysis as suggested by the Panel. The intent is to include the agents in a class that reflects their primary use. But the therapeutic classes also have to be rational.

A staff member commented that one of the reasons why there are apples and oranges is that every class the Committee selects has to have either a basic core formulary (BCF) agent or an extended core formulary (ECF) agent.

Dr. Hutchings said that answers the question as far as he is concerned.

The meeting was adjourned by the Chair at 11:30 a.m.

Brief Listing of Acronyms Used in This Summary

Abbreviated terms are spelled out in full in this summary; when they are first used, the acronym is listed in parentheses immediately following the term. All of the terms used as acronyms are listed below for easy reference. The term "Panel" in this summary refers to the "Uniform Formulary Beneficiary Advisory Panel," the group whose meeting is the subject of this report.

- A1c — Hemoglobin type A1c
- ACG — American College of Gastroenterology
- ACS — Acute coronary syndrome
- BAP — Uniform Formulary Beneficiary Advisory Panel (the "Panel" referred to above)
- BCF — Basic Core Formulary
- BIA — Budget Impact Analysis
- CCB — Calcium channel blockers (a drug class)
- CEA — Cost-effectiveness analysis
- C.F.R — Code of Federal Regulations
- CHD — Coronary heart disease
- CMA — Cost-Minimization Analysis
- DFO — Designated Federal Officer
- DM — Diabetes mellitus
- DOD — Department of Defense
- ECF — Extended Core Formulary
- ER — Extended Release (a drug formulation)
- ESI — Express-Scripts, Inc.
- FACA — Federal Advisory Committee Act
- FDA — U.S. Food and Drug Administration
- FPG — Fasting plasma glucose
- GERD — Gastro-esophageal reflux disease
- GI — Gastro-intestinal
- H2 — Histamine-2 antagonists (a drug class)
- HDL — High-density lipoprotein
- HMO — Health Maintenance Organization
- IV — Intravenous
- LDL — Low-density lipoprotein
- LIP-1 — Antilipidemic (a drug class)
- MHS — Military Health System
- MI — Myocardial infarction
- MTF — Military Treatment Facility
- NNH — Number Needed to Harm
- NNT — Number Needed to Treat
- OTC — Over the counter
- PA — Prior Authorization

- P&T Committee — DOD Pharmacy and Therapeutics Committee
- PDTS — Pharmacy Data Transaction Service
- PEC — DOD Pharmacoeconomic Center
- PPI — Protein pump inhibitors (a drug class)
- RCTs — Randomized Control Trials
- T2DM — Type 2 diabetes mellitus
- TC — Total cholesterol
- TG — Triglycerides
- TMA — TRICARE Management Activity
- TMOP — TRICARE Mail Order Pharmacy
- TRRx — TRICARE Retail Pharmacy Program
- TZD — Thiazolidinedione (a drug class)
- UF — DOD Uniform Formulary
- U.S.C. — United States Code
- VA — U.S. Department of Veterans Affairs

Uniform Formulary Beneficiary Advisory Panel

Meeting Summary
September 21, 2006
Washington, D.C.

Panel Members Present:

- John Class, Military Coalition, Chairman
- Kathryn Buchta, TRICARE Network Provider
- Deborah Fryar, Military Coalition
- Marshall Hanson, National Military and Veterans Alliance
- Sydney Hickey, Military Coalition
- Rance Hutchings, Uniformed Services Family Health Plan
- Lisa Le Gette, TRICARE Retail and Mail-Order Pharmacy Contracts
- Jeffrey Lenow, Medical Professional
- Jan Prasad, TRICARE Network Provider
- Charles Partridge, National Military and Veterans Alliance
- Marissa Schlaifer, Medical Professional

The meeting was held at the Naval Heritage Center Theater, 701 Pennsylvania Ave., N.W., Washington, D.C. Major (MAJ) Travis Watson, the Designated Federal Officer (DFO), called the proceedings to order at 8:00 a.m.

MAJ Watson indicated this meeting of the Panel has been convened to discuss and review the recommendations of the Department of Defense (DOD) Pharmacy and Therapeutic (P&T) Committee meeting held on August 15-17, 2006 in San Antonio, TX.

Agenda

The agenda for the June meeting of the Panel is:

- Opening remarks and public comments
- Consideration of antilipidemic (LIP-1) drug class recommendations
- Consideration of thiazolidinedione (TZD) drug class recommendations
- Consideration of histamine-2 (H2) antagonist and other gastrointestinal (GI) protectants drug class recommendations
- Consideration of Byetta prior authorization (PA) recommendations
- Wrap-up comments

Opening Remarks

MAJ Watson stated that under 10 United States Code (U.S.C.) section 1074g the Secretary of Defense is required to establish a DOD Pharmacy and Therapeutics (P&T) Committee for the purpose of establishing a Uniform Formulary (UF) of pharmaceutical agents, review the formulary on a periodic basis and make additional recommendations regarding the formulary as the Committee deems necessary and appropriate.

10 U.S.C. section 1074g also requires the Secretary to establish a Uniform Formulary Beneficiary Advisory Panel (BAP) to review and comment on the development of the Uniform Formulary. The Panel shall include members that represent non-governmental organizations and associations that represent the views and interests of a large number of eligible covered beneficiaries. Comments from the Panel must be considered before implementing changes to the Uniform Formulary. The Panel's meetings are conducted in accordance with the Federal Advisory Committee Act (FACA).

The duties of the Uniform Formulary Beneficiary Advisory Panel are:

- To review and comment on the recommendations of the P&T Committee concerning the establishment of the Uniform Formulary and subsequent recommended changes. Comments to the Director, TRICARE Management Activity (TMA), regarding recommended formulary status, pre-authorizations, and suggested dates for changing from "formulary" to "non-formulary" status must be reviewed by the Director before making a final decision.
- To hold meetings in an open forum quarterly. The Panel may not hold meetings except at the call of or with the advance approval of the Chairman of the Panel.
- To prepare minutes of the proceedings and prepare comments for the Secretary or his designee regarding the Uniform Formulary or changes to the Formulary. The minutes will be available on the website and comments will be prepared for Dr. Winkenwerder.

As guidance regarding this meeting, MAJ Watson said the role of the Beneficiary Advisory Panel is to comment on the Uniform Formulary recommendations made by the P&T Committee at their last meeting, August 15-17, 2006. While the Department appreciates that the BAP may be interested in the drug classes selected for review, drugs recommended for the basic core formulary (BCF) or specific pricing data, these topics do not fall under the purview of the BAP.

The P&T Committee met for approximately 20 hours to consider the class review recommendations presented today. Since this meeting is considerably shorter, the Panel will not receive the same extensive information that is presented to the P&T Committee members. However, the BAP will receive an abbreviated version of each presentation and its discussion.

Detailed minutes of this meeting are being prepared. The BAP minutes, the DOD P&T Committee meeting minutes and Dr. Winkenwerder's decisions will be available on the TRICARE website in approximately four weeks.

MAJ Watson next reviewed the ground rules for conducting the meeting:

- All discussion takes place in the open public forum. There is to be no committee discussion outside the room, during breaks or at lunch.
- Audience participation is limited to private citizens who signed up to address the Panel.
- Members of the Pharmacoeconomic Center (PEC) and the P&T Committee are available to answer questions related to the BAP's deliberations. Should a misstatement be made, these individuals may interrupt to ensure that the minutes accurately reflect relevant facts, regulations or policy.

MAJ Watson introduced the members of the Beneficiary Advisory Panel present, including a new member, Kathryn Buchta of Health Net Federal Services (replacing Dr. Miller). He also introduced individuals in the audience who might be participating in the session.

MAJ Watson then briefly reviewed housekeeping considerations.

Private Citizen Comments

MAJ Watson opened the meeting for private citizen comments. There was no response.

Opening Remarks by the Chair

The Panel Chairman, Mr. John Class, noted that the Panel received a briefing in March on the results of the reviews so far and reminded the staff that the Panel is still looking for data on actual savings. MAJ Watson said that the requested information is being prepared – the staff is updating the same information for Dr. Winkenwerder and is planning to synchronize the two presentations.

Presentation on Antilipidemic (LIP-1) Drug Class Review

Clinical Effectiveness Review

Major (Maj) Wade Tiller, Deputy Director of the Pharmacoeconomic Center (PEC), opened the presentation by introducing the presenting staff: Lieutenant Colonel (Lt Col) Jim McCrary, Dr. Harsha Mistry and Dr. Julie Liss, all of the PEC Clinical Operations Staff, and Commander (CDR) Michelle Perello, a member of the P&T Committee, who will provide the Panel with the physician's perspective.

[Insert script, pages 1 through 11]

Cost Effectiveness Review, Antilipidemic (LIP-1) Drug Class, and Recommendations

Maj Tiller presented the cost effectiveness review and P&T Committee recommendations for the LIP-1 drug class.

[Insert script, pages 12 through 14]

Physician Perspective

CDR Perello discussed the physician's perspective, commenting that the briefers had done a very good job of presenting the pros and cons of the medications from a clinical perspective. In regard to Crestor, she said there were some indications that warrant further monitoring but acknowledged that there may be some patients who actually need it.

Dr. Lenow asked for clarification about including Vytorin being in the statin drug class. He said it is not a statin *per se*, even though it is included in the class as a term of art. He also noted that amlodipine, classified as non-formulary earlier, is included along with atorvastatin in the

combination drug Caduet. He said the presentation sounded like the cost to the government would be higher if the drug was kept on formulary. He questioned what the overall cost effect would be for the end user, who is on a calcium channel blocker, of having to have scripts written separately for the generic equivalent of amlodipine and atorvastatin compared to the cost of a single script for Caduet.

Maj Tiller said the PEC recognizes that Vytorin is not a statin, but decided to include it in that sub-class for purposes of Uniform Formulary evaluation so it would be compared along with intensive-dose statins. Regarding the cost of separate scripts, Maj Tiller replied that both Zocor and a generic calcium channel blocker are available in generic form. If a patient elected to have two prescriptions filled instead of one, the total co-pay would be \$6.00 (versus \$9.00 for the brand product co-pay of the combination drug if it were on formulary).

Dr. Lenow observed that the trade-off, in that case, would be compliance. He cited an earlier study showing that only about one-third of the patients who need to be on these drugs are actually on them, and only half of that group are at goal. Compliance is a big issue for him. With the higher impact statins, not only are patients not reaching goal, but the guidelines have been adjusted, making physicians more aggressive in their low-density lipoprotein (LDL) goals, especially with diabetics. Anything that can intensify the impact of LDL-lowering has to be taken very seriously. His concern about Crestor being non-formulary is that it does have high impact potential.

CDR Perello pointed out that Crestor will still be available for the very small part of the Military Health System (MHS) population that really needs it.

Dr. Prasad said that, as a practicing cardiologist, his experience is that you can count the number of patients using Crestor on one hand. Physicians can do anything with Zocor and Vytorin that they can do with Crestor. He isn't concerned about having Crestor classified as non-formulary.

Panel Discussion of Antilipidemic (LIP-1) Drug Class Recommendations

Mr. Class opened the subject for general discussion among the Panel.

Dr. Hutchings pointed out that today's agenda doesn't call for moving a lot of drugs to the third tier. He observed that the discussion of Crestor had centered on the drug in a 40 mg dosage, but that Crestor in lower doses had turned out to be cost-effective. He asked if there had been any discussion of restricting only Crestor-40 and not other formulations. He also said that a comment had been made that when the 6-month exclusivity for Zocor expires there will be other statins in that class that should be looked at. Noting that this is the most expensive class of drugs – involving many millions of dollars – he asked whether consideration was being given to moving other drugs to third tier in a few months. He asked for clarification of why so few drugs are being classified as non-formulary and why Crestor was being classified as non-formulary in all its formulations.

Maj Tiller said the Committee had looked at splitting out the decision on Crestor by doses. The evaluation showed that this approach would not be a good alternative. As to why the recommendations were not more restrictive, Maj Tiller said that the P&T Committee looked at the class in May to construct a conceptual approach for how to evaluate that class. The Committee was very adamant about having at least one high-intensity LDL-lowering agent

available on the Uniform Formulary. That meant that Zocor plus at least one other agent would have to be on the Uniform Formulary. When bids were submitted by manufacturers, the PEC chose a scenario that provided the greatest economic benefit for the MHS. Many different types of scenarios were considered, but the one recommended provided the greatest benefit. A large number of people do not get their prescriptions filled at the military treatment facility (MTF), but at retail and mail order. The PEC has demonstrated the ability to move market share at the MTF, but it doesn't have the same ability at the other points of service (although it is able to move some market share). Because of that, making other drugs non-formulary at the other two points of service is not always cost-beneficial to the MHS.

Captain (CAPT) Richerson said that PEC is very sensitive to the issue. The MHS objective, and that of other health plans, is to optimize the use of simvastatin (Zocor) where it is clinically focused. He said there are utilization thresholds for the use of simvastatin and that PEC will be watching like a hawk. The recommendation provides unfettered access to a broad array of products in the class. If physicians need the high-intensity agent they will be able to get to it without a lot of hurdles. If the utilization of simvastatin crosses over the threshold, the Committee could very easily go back and re-look at this class and adopt utilization management tools. But in this case it was judged to be not necessary at this time.

Mr. Hanson suggested that moving Crestor to non-formulary was an action that would not really bring about much cost saving. Rather, it seems to be some sort of exercise. His view is that tracking patients who really need Crestor will show that they will be getting the medical necessity exemption anyway. He believes what's going to happen is that MHS will still be prescribing it under medical necessity and there won't be any cost savings. He said that is something to track and be aware of.

Maj Tiller replied that the MHS experience to date has been that the majority of people on a non-formulary drug who elect not to move to a formulary drug simply pay the \$22 co-pay and don't seek a medical necessity. Very few people use the medical necessity process, even though it reduces the cost to a \$9 co-pay.

Ms. Le Gette agreed with Maj Tiller, saying that what he described is exactly what her organization is seeing. It's probably because of the co-pay differential – other plans have co-pay requirements that range from \$45 to \$75.

Mr. Hanson said that it also indicates a need for the associations to do a better job of educating people about what their options are. If the beneficiary feels it's a medical necessity and the doctor confirms it, they should be taking advantage of it rather than paying the higher cost.

Ms. Hickey said the associations also need to do a better job of educating beneficiaries on the mail order pharmacy because there isn't any automatic way for beneficiaries who are using retail to understand that they are going to save money with the mail order. A lot of people don't use it because they just don't know about it. She also disagreed that people *choose* not to use the MTF for their pharmacy. A great many beneficiaries are unable to use MTFs because they can't get an appointment to get a prescription so they can use the MTF. Mr. Hanson added that they may also reside a long distance away from an MTF, making other sources more economical, even though they would love to use it.

Ms. Le Gette asked about the current PA requirement for certain statins. She asked if that would terminate when the implementation date is set for this class. The answer was affirmative. She also asked about Zocor, which has been termed the "workhorse statin." She asked if the PEC now thinks that market share for a product like Lipitor will increase at the MTF. Maj Tiller acknowledged that it is a concern, as CAPT Richerson had said earlier, and the PEC will monitor the situation very closely.

Dr. Prasad asked for clarification about the cost difference between Lipitor and Crestor. Maj Tiller answered that both were considered to have the same relative cost-effectiveness. He said three of the four models used the intermediate outcome measure of LDL or total cholesterol to high-density lipoprotein (HDL) ratio. Given Crestor's ability to lower cholesterol more than Lipitor, it was slightly more effective, and it was competitively priced. But when you look at the big picture, they both had similar relative cost-effectiveness. The "big picture" includes other considerations, such as the budget impact analysis, the scenario with Lipitor on formulary and Crestor not on formulary was more favorable for the MHS overall. CDR Perello added that from a clinical standpoint there also was a preference for Lipitor over Crestor. If the clinical data had favored Crestor over Lipitor, the Committee would have gone with Crestor, but that wasn't the case.

Dr. Hutchings asked for a clarification on the significance of the February 1 date included in the recommendation. If the Panel was to recommend that the implementation period should be six months, he asked if that would put DOD in a pickle. The answer is that the February 1 date results from a contractual agreement reached between DOD and the supplier, so anything beyond that would cause difficulties.

Ms. Fryar asked for clarification about the implementation plan statement that MTFs may fill prescriptions for patients who have been referred to non-MTF providers as long as medical necessity has been established. Specifically, she asked about patients who are going to non-MTF providers under TRICARE standard, if they are eligible to have the prescription filled at the MTF. The answer was that they are not.

Panel Vote on Antilipidemic (LIP-1) Drug Class Formulary Recommendations

Mr. Class next called for a panel vote on the formulary recommendation for this drug class:

"Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Antilipidemic 1 agents, and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted to recommend that atorvastatin (Lipitor), fluvastatin immediate and extended release (Lescol, Lescol XL), pravastatin (Pravachol, generics), simvastatin (Zocor, generics), lovastatin immediate and extended release (Mevacor, generics; Altoprev), lovastatin/niacin (Advicor), ezetimibe/simvastatin (Vytorin), niacin immediate and extended release (Niacor, Niaspan), and ezetimibe (Zetia) be maintained as formulary on the UF and that rosuvastatin (Crestor) and atorvastatin/amlopidine (Caduet) be classified as non-formulary."

The Panel voted unanimously (10-0) to concur with the P&T Committee's recommendation.

Panel Discussion of Implementation Plan Recommendations for the Antilipidemic (LIP-1) Drug Class

Ms. Schlaifer asked about the need to make the change sooner rather than later. Specifically she asked whether the two drugs are married as far as the implementation date is concerned. With the statin alone, if the formulary misses compliance by a couple of days there won't be a big problem. But with the amlodipine combination, it might be more of an issue if someone misses a couple of days' doses. The question is whether the implementation of both must be handled on one date or can they be split. MAJ Watson replied that there must be one implementation date.

Mr. Class read into the record an e-mail received from a beneficiary regarding implementation notification:

“Chairperson, Uniform Formulary Beneficiary Advisory Panel:

I am very concerned that there is no process for notification of individuals who are already taking a particular maintenance medication that had been on the formulary, when that medication is deleted.

I had been on a medication for a period of time that was removed from the formulary several months ago. I found out only by chance when I called Express Scripts on another issue while transitioning the rest of my medications to TMOP, and heard on the opening menu message that it had been deleted. I received no notification and would have had a very rude awakening had I ordered a refill and then had to pay \$22.00 rather than the \$9.00.

I have used the formulary site to check new medications, but had been taking the particular medication for over a year. Until recently, I was not aware of the availability of the information-specific TMA mailing list subscriptions, but have subsequently subscribed to receive the press releases pertaining to formulary changes. I had gotten TRICARE information emails in the past (none recently), but if I recall correctly, they were about reporting fraud and such. There had not been any information relating to formulary changes.

That said, how does an individual, especially our elderly, non-computer literate veterans get this vital information?

I do not believe that it is proper to put an individual in the position of ordering medication refills, then having that "rude awakening" I mentioned with a co-pay of \$22.00 rather than \$9.00. This is especially the case, with those elderly individuals who are in no position to be able to absorb even that (to most of us) relatively small increase in cost. Anyone who does not have access to a computer and has no need to call Express Scripts is in that very position.

I request discussion and consideration of a process by which beneficiaries are notified when changes to the formulary impact the medications which they are taking.

Thank you in advance for your reply.”

[Name redacted]

Mr. Class reiterated a concern related to the above that the Panel has voiced all along – that notification relies on the associations. Unless people are internet-savvy, they don't find out about changes until they get to the point of delivery. For their publications, the associations generally need a good three or four months from the time a decision is made to get the notice out. He said this e-mail is very typical of what the associations hear from their members.

Panel Vote on Implementation Plan Recommendation for the Antilipidemic (LIP-1) Drug Class

Mr. Class read the P&T Committee recommendation:

“The P&T Committee recommended an effective date no later than the first Wednesday following a 90-day implementation period. The implementation period will begin immediately following the approval by the Director, TMA.”

The Panel vote was: 8 concur and 2 non-concur.

Mr. Hanson commented that, while he supports the recommendation, he hopes that in reviewing it TMA will take it out to the maximum time frame, which will be close to the February 1, 2007 date to allow the word to get out to the beneficiaries.

Mr. Class said the way he hears that comment is that Mr. Hanson basically does not concur with the recommendation. Mr. Hanson clarified by noting that because of adherence to contract limitations (the February 1, 2007 date), some members of the Panel feel that their hands are tied.

Dr. Hutchings said that the difference is only about a week.

Mr. Class said he, as a Panel member, isn't concerned with DOD contract dates. That shouldn't enter into the Panel's consideration. The question is: “What does the Panel think the implementation time frame should be?” In other words, whether everybody agrees with the 90-day implementation period. The statement that the time frame should be pushed out as far as possible suggests that there is disagreement with the 90-day implementation period.

Mr. Class referred back to the discussion at the June meeting of the Panel, at which the instruction was for the Panel to deal with the recommendations submitted by the Committee. If the Panel feels more time is necessary, it should non-concur with the recommendation and provide comments.

Dr. Hutchings said his reading of the recommendation was that the plan was for implementation in “90 days, no later than February 1.” That was the recommendation that was stated from the podium.

Maj Tiller clarified that the recommendation is for “no sooner than 90 days, no later than 1 February, 2007.”

Mr. Class questioned the “no later than February 1” clause, pointing out that the material received says something different. He said he doesn't understand the clause. Heretofore, the

recommendations have always been for a set number of days from approval of the recommendation.

A P&T staff member clarified that the Committee voted, at the meeting itself, for implementation in "no earlier than 90 days." They were aware that the current statin contract entered into by DOD had not been resolved with Merck as far as a clean exit strategy, so the Committee said "no earlier than." Discussions with Merck over the last couple of weeks have agreed to formally terminate the contract February 1, 2007. It is a joint contract with the Veterans' Affairs (VA) and all parties have agreed to that time. So the additional date of February 1 reflects the contract resolution.

Ms. Hickey commented that this discussion again brings up the subject that has been discussed at every meeting of the Panel so far. There has to be a process for notifying beneficiaries. When beneficiaries are notified of the changes and their implementation dates, concern over the implementation dates will begin to wane because beneficiaries will have enough time to make reasonable decisions. Right now, the beneficiaries' time frame is normally when they send in their renewal to Express Scripts or refill their prescription at the retail pharmacy. That's hardly enough time to make a decision on what you want to do. A review of the comments made on implementation over the months that the Panel has been in existence will show that has consistently been the problem – beneficiaries were not provided notification in enough time.

Mr. Hanson commented that the question also brings up another issue the Panel has raised in the past – the voting structure itself. One of the Panel members raised the issue of having two drugs voted into non-formulary status on the same timetable. An option could have been included to put the agents on different timetables. In the past people have also voted for the positive or the negative because of the inclusion or exclusion of a drug presented to the Panel. The voting system is inflexible and can result in people voting in ways opposite to how they want to vote. He said in this case many Panel members would like to vote for a longer implementation period but feel they don't have any choice but to support DOD at this time.

MAJ Watson commented that he thinks the Chairman's approach is the correct one. The judgment of the Panel is what it is, up to 180 days. That judgment should be put in the record as a comment.

Mr. Class said what he has on his sheet is the official recommendation of the P&T Committee. What he is hearing now is that it is not the "official recommendation." If the P&T has a different published recommendation, that's what the Panel needs to vote on.

Mr. Lynn Burlison, TMA General Counsel's office, affirmed that Mr. Class' position is the correct one, i.e. the Panel is to vote on the official P&T recommendation that came out of the meeting.

Mr. Class acknowledged that there is a contract issue, but that the Panel needs to vote on the 90-day recommendation. Ms. Hickey said she thinks the Panel should re-vote because it was taking into account the February 1 deadline before.

Dr. Buchta asked whether the Panel has any authority to change processes for notifying beneficiaries. Mr. Class answered in the negative. Dr. Buchta then asked whether the implementation date should be "held hostage" for notification of beneficiaries, which seems to

be the main issue. Mr. Class replied that the only authority the group has is to non-concur with the recommendation (the implementation date in this case). A year and a half ago when the Panel first met it raised the issue of DOD having no notification process. Dr. Buchta asked what would be gained by extending the implementation date to 120 or 180 days. Mr. Class replied that it would give the associations a chance to get notification into its magazines and get the information about changes in the formulary out to members. If DOD made a separate notification directly to beneficiaries there would be no issue. Dr. Buchta asked how many of the applicable beneficiaries are reached by the association publications. Mr. Class said his organization's magazine reaches 370,000 people, but that isn't the issue. The issue is that there is no DOD notification to the beneficiaries.

Ms. Fryar commented that she doesn't believe it should be the responsibility of the associations to get the information out to the beneficiaries. That should be a TRICARE job.

Ms. Hickey added that, from the beginning, when the Panel has raised questions on implementation dates and has recommended changes on several, almost all have been based on the issue of beneficiary notification. The Panel has felt that it was correct and fair to inform Dr. Winkenwerder that its decision was not necessarily made on a clinical basis, but on the basis that patients needed to have a little bit more lead time in order to make informed decisions.

Mr. Hanson noted that the Panel's name is the "Beneficiary Advisory Panel." Technically, it cannot "hold hostage." It doesn't have that authority; it simply advises the Secretary, who has the authority and makes the decisions.

MAJ Watson made an official correction to the P&T Committee recommendation as written. Where the effective date says "no *later* than" the wording should read "no *earlier* than." The remainder of the recommendation is correct.

Mr. Class said that is too ambiguous a recommendation. MAJ Watson said it reflects the uncertainty about how the current contract issue was going to be resolved. All they knew at the time of the meeting was that it would be no earlier than 90 days.

Re-Vote on Implementation Plan Recommendation

Mr. Class read the P&T Committee's corrected recommendation:

"The P&T Committee recommended an effective date no earlier than the first Wednesday following a 90 day implementation period. The implementation period will begin immediately following approval by the Director, TMA."

The Panel vote was: concur 6 and non-concur 4.

Note: Mr. Partridge arrived late and did not vote on this drug class.

Comments on Panel Vote

Ms. Fryar commented that she is concerned that the issue is tied to a contract. The Panel is making recommendations for the beneficiaries in regard to the implementation plan. The Panel vote reflects the standardized approach that it has taken to date. If it knew that formal

notification of beneficiaries was in place, the Panel would be much more likely to support the recommended implementation time frames.

Mr. Class agreed with the comment, stating that if DOD had a notification process there would be fewer “non-concur” votes.

Dr. Buchta asked whether the Panel could make a recommendation to Dr. Winkenwerder to consider directing his management activity to address the notification process or lack thereof. Mr. Class agreed that the Panel could do so again.

As an aside, Dr. Hutchings asked whether there is any reason why data can't be pulled from the Pharmacy Data Transaction Service (PDTS) to create mailings. That would allow notification to be sent out very quickly – three days – informing people about what their options are no matter how many patients are involved.

Presentation on Thiazolidinedione (TZD) Drug Class Review

Clinical Effectiveness Review

Maj Tiller introduced Dr. Julie Liss and Lt Col McCrary to present the clinical effectiveness review for the Thiazolidinedione (TZD) Drug Class.

[Insert script, pages 15-21]

Cost Effectiveness Review of the (TZD) Drug Class and Recommendations

Next, Maj Tiller presented the cost effectiveness review and P&T Committee recommendations for this drug class.

[Insert script, pages 22 and 23]

Physician Perspective

CDR Perello provided the Panel with the physician's perspective on the P&T Committee's review and recommendations in this drug class. She said she didn't have anything to add to the presentation but would be happy to answer clinical questions.

Mr. Partridge asked whether CDR Perello had actually prescribed drugs in this class and, if so, whether she had a favorite. CDR Perello said she had prescribed drugs in this class and did not have a favorite. She said she didn't think physician preference would be a big issue. Most diabetics are on statins anyway, so the approach is going to be to try one and see how the patient does. If there is a drug interaction, the physician will switch to the other available agent.

Panel Questions and Discussion

Ms. Hickey questioned Maj Tiller about the two P&T Committee votes to abstain. She noted that this is somewhat unusual. Maj Tiller confirmed the Committee vote on the recommendation.

Mr. Hanson commented that the presenters had done an excellent job and that he appreciated the fact that the presentation moved quickly. He also noted that the recommendation in this case was not to move any agents to non-formulary. He asked whether such cases in the future might be summarized even more briefly. He pointed out that the only action available to the Panel would be to not accept the recommendation, which would mean that someone on the Panel believes there is a drug within the category that should be classified as non-formulary. Most of the Panel members do not have the expertise to make such a recommendation. Those who do would still be free to bring in their questions and get into the details. But if no one on the Panel has any disagreement with the recommendations, the review and discussion process should be very quick as the subject matter would be non-controversial.

MAJ Watson replied that there is no reason that can't be done. He said he would discuss it with the Chair for future classes.

Dr. Hutchings, while agreeing, noted that it is useful to have the background information. He likes the "read ahead" material in its present form. Mr. Hanson agreed, noting that it would provide the basis for questions.

Panel Vote on Thiazolidinedione (TZD) Drug Class Recommendations

Mr. Class read the recommendation:

"The P&T Committee, based upon its collective professional judgment, voted to accept the TZD cost analysis presented by the PEC. The P&T Committee concluded that the UF scenario that maintained rosiglitazone (Avandia), pioglitazone (Actos), rosiglitazone/metformin (Avandamet), pioglitazone/metformin (Actoplus Met), and rosiglitazone/glimepiride (Avandaryl) on the UF formulary was the most cost effective UF scenario considered."

The Panel voted unanimously (11-0) to concur with the recommendation.

Presentation on Histamine-2 (H2) Antagonists and Other Gastrointestinal (GI) Protectants Drug Class Review

Clinical Effectiveness Review

Maj Tiller introduced Dr. Harsha Mistry to present the H2 antagonists and other GI protectants' clinical effectiveness review.

[Insert script, pages 24 through 27]

Cost Effectiveness Review and P&T Committee Recommendations

Maj Tiller presented the cost effectiveness review results and the P&T Committee recommendations for this drug class.

[Insert script, page 28]

Physician Perspective

CDR Perello answered the Panel's clinical questions.

Dr. Lenow commented that the use of cimetidine is very low. He noted that there was a time when the community was discussing cimetidine's potential side effect of disorientation on the elderly. He said he has seen it personally. The effect may have been caused by a free radical in the structure of cimetidine that is somewhat similar to LSD. He said there are so many choices available in this drug class that if he was voting on cimetidine he would vote to keep it on formulary only for its other uses.

CDR Perello said there are people in the community who do use it for other uses, such as allergy.

Panel Discussion and Vote on Histamine-2 (H2) Antagonists and Other Gastrointestinal (GI) Protectants Drug Class

There was no Panel discussion of the recommendation in this drug class.

Mr. Class read the P&T Committee recommendation:

"Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the H2 antagonists & other GI protectants, and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted to recommend that the H2 antagonists ranitidine (Zantac, generics), cimetidine (Tagamet, generics), famotidine (Pepcid, generics) and nizatidine (Axid, generics); the prostaglandin analog misoprostol (Cytotec, generics); and the mucosal protective agent sucralfate (Carafate, generics) should be maintained on the UF and that no agents from this class be classified as non-formulary."

The Panel voted unanimously (11-0) to concur with the recommendation.

Presentation on Prior Authorization Requirements for Byetta

Maj Tiller introduced Dr. Liss to present the prior authorization (PA) requirements for Byetta.

[Insert script, pages 29 & 30]

Panel Questions and Discussion of the Byetta PA

Ms. Le Gette asked if it is the case that the PA will not be implemented until the automated system is ready to go. The answer is that MHS is anticipating that PDTS will provide a PA capability in many areas. Ms. Le Gette asked if the intent is to have all of the current users of Byetta obtain a PA or will they be grandfathered. The answer was that all would have to have a PA.

Dr. Lenow noted that the PA would require evidence that a patient had failed on metformin or a sulfonylurea, but the criteria do not list TZD. He asked why. The answer was that the Food and Drug Administration (FDA) approved the use of Byetta with TZDs. Dr. Lenow observed that

the concern here is that, lacking the evidence required for the PA, the assumption is that Byetta is being used for the wrong reason – weight loss, primarily. He asked if that is being done for other situations, such as Topamax. Maj Tiller answered that other situations are being evaluated on a case-by-case basis. He said he has seen the *Wall Street Journal* article about Topamax being used for weight loss, but Topamax hasn't yet appeared on the PEC's radar. If there is evidence that it is becoming a problem, the P&T would address it. Dr. Lenow also noted that Topamax has a higher unit cost that would make it more of a "red flag" than some others. Maj Tiller added that the PEC looked at Byetta not long ago as a new drug and recognized then that it would need to be monitored because of its potential for weight loss.

Dr. Lenow commented that the philosophy behind the new approach to diabetes relies on oral agents that may make the Byetta discussion moot. He said there is a pipeline of 6 or 7 new agents ready to be approved. Dr. Liss said it is still too early to tell how the new agents will fit in with the treatment programs.

Dr. Hutchings asked if the automated program would reject Byetta for patients who are on insulin now. The answer provided was that it is currently being studied, but insulin is not currently a supplement. Dr. Lenow added that the theory is that it would offset the use of insulin. Dr. Hutchings said his concern is whether the PDTS would have the capability to reject a PA based on a red flag should a conflict pop up.

Ms. Schlaifer asked what happens at the community pharmacy level. Does the system send a message back that tells them to let the patient know they need a prior authorization? The answer was that it does.

Ms. Fryar asked about the 10 percent of patients that are currently using Byetta who would not meet the automated criteria – how many would seek to continue treatment and whether they would be grandfathered in. The answer provided was that MHS doesn't know how many patients will actually want to be continued when a PA is required. They are anticipating that only a small number of patients will be affected by the decision.

Panel Vote on the Byetta PA Recommendation

Mr. Class read the implementation plan recommendation:

"The Committee recommends that the PA should have an effective date no sooner than the first Wednesday following a 30-day implementation period, but as soon thereafter as possible based on availability of the automated PA capability in PDTS. The implementation period will begin immediately following the approval by the Director, TMA."

Discussion

Ms. Hickey commented that the recommendation says two different things. One is that Dr. Winkenwerder has to approve it before the process starts. The other is that the PDTS has to be up and running. She asked which condition is germane.

The answer was that the implementation will be no sooner than 30 days, but it could be later, depending on the availability of the PDTS.

Ms. Hickey said she isn't sure that both conditions should be in the recommendation. Dr. Buchta commented that she agrees that the automated system should be in place first.

Ms. Hickey said the recommendation could be fixed by saying that "the implementation period will begin immediately following the approval by the Director and the recognized capability of PDTS." She said she is a little skeptical about how fast the PDTS is going to be operational.

The Panel voted unanimously to concur with the recommendation.

The Panel included a comment that implementation should begin immediately following operational PDTS implementation and approval by the Director, TMA.

Panel Vote on PA Criteria

Mr. Class read the P&T Committee recommendation:

"The committee agreed that the following PA criteria should apply. Patients meeting the automated PA criteria would not be required to have their providers submit any additional information and in all likelihood would not even be aware of the existence of the PA. PA approvals would be valid indefinitely.

- 1) Automated PA criterion:
 - Patient has received any oral antidiabetic agent in the last 120 days.
- 2) PA criteria if automated criterion is not met:
 - Coverage is approved if the patient meets both of the following criteria:
 - Diagnosis of type 2 diabetes mellitus (DM)
 - Patient has not achieved adequate glycemic control on metformin, a sulfonylurea, or a combination of metformin and a sulfonylurea."

Dr. Hutchings asked about the PA being "indefinite" and whether a patient who has a PA for a drug that goes generic would still allow them to obtain the brand drug. The answer was that the PA would be superseded and people will not be grandfathered into branded products.

The Panel voted unanimously (11-0) to concur with the recommendation.

Closing Remarks

MAJ Watson announced that the next meeting will be December 20 at 8:00 a.m. at the Naval Heritage Center in Washington, D.C. Formal announcement will be posted in the *Federal Register*.

Dr. Hutchings commented that it looks like the process is starting to combine a lot of classes. This sometimes confuses matters when the Panel votes. For example, he sees GI protectants and H2 blockers as two completely different beasts. Also niacin and statins. He asked if there is any way that the Panel could vote separately in such cases. He is uncomfortable being asked to vote on one set of combined recommendations.

The General Counsel answered that the Panel must vote on the recommendation that comes out of the P&T Committee. But it can make comments that differentiate sub-classes.

Mr. Class asked whether the Panel could make a recommendation that the P&T Committee should review how it structures its recommendations. Mr. Burleson agreed that would be appropriate.

CAPT Richerson said that a lot of consideration goes into how the P&T Committee decides what constitutes a particular drug class. The matter of where to classify a particular drug is a problem that will occur over and over again. From a therapeutic standpoint, it's hard to say where a lot of these drugs should be classified. It may not be practical to restructure the review and analysis as suggested by the Panel. The intent is to include the agents in a class that reflects their primary use. But the therapeutic classes also have to be rational.

A staff member commented that one of the reasons why there are apples and oranges is that every class the Committee selects has to have either a basic core formulary (BCF) agent or an extended core formulary (ECF) agent.

Dr. Hutchings said that answers the question as far as he is concerned.

The meeting was adjourned by the Chair at 11:30 a.m.

Brief Listing of Acronyms Used in This Summary

Abbreviated terms are spelled out in full in this summary; when they are first used, the acronym is listed in parentheses immediately following the term. All of the terms used as acronyms are listed below for easy reference. The term "Panel" in this summary refers to the "Uniform Formulary Beneficiary Advisory Panel," the group whose meeting is the subject of this report.

- A1c — Hemoglobin type A1c
- ACG — American College of Gastroenterology
- ACS — Acute coronary syndrome
- BAP — Uniform Formulary Beneficiary Advisory Panel (the "Panel" referred to above)
- BCF — Basic Core Formulary
- BIA — Budget Impact Analysis
- CCB — Calcium channel blockers (a drug class)
- CEA — Cost-effectiveness analysis
- C.F.R — Code of Federal Regulations
- CHD — Coronary heart disease
- CMA — Cost-Minimization Analysis
- DFO — Designated Federal Officer
- DM — Diabetes mellitus
- DOD — Department of Defense
- ECF — Extended Core Formulary
- ER — Extended Release (a drug formulation)
- ESI — Express-Scripts, Inc.
- FACAA — Federal Advisory Committee Act
- FDA — U.S. Food and Drug Administration
- FPG — Fasting plasma glucose
- GERD — Gastro-esophageal reflux disease
- GI — Gastro-intestinal
- H2 — Histamine-2 antagonists (a drug class)
- HDL — High-density lipoprotein
- HMO — Health Maintenance Organization
- IV — Intravenous
- LDL — Low-density lipoprotein
- LIP-1 — Antilipidemic (a drug class)
- MHS — Military Health System
- MI — Myocardial infarction
- MTF — Military Treatment Facility
- NNH — Number Needed to Harm
- NNT — Number Needed to Treat
- OTC — Over the counter
- PA — Prior Authorization

- P&T Committee — DOD Pharmacy and Therapeutics Committee
- PDTS — Pharmacy Data Transaction Service
- PEC — DOD Pharmacoeconomic Center
- PPI — Protein pump inhibitors (a drug class)
- RCTs — Randomized Control Trials
- T2DM — Type 2 diabetes mellitus
- TC — Total cholesterol
- TG — Triglycerides
- TMA — TRICARE Management Activity
- TMOP — TRICARE Mail Order Pharmacy
- TRRx — TRICARE Retail Pharmacy Program
- TZD — Thiazolidinedione (a drug class)
- UF — DOD Uniform Formulary
- U.S.C. — United States Code
- VA — U.S. Department of Veterans Affairs