Department of Defense
Pharmacoeconomic Center

2421 Dickman Rd., Bldg. 1001, Rm. 310
Fort Sam Houston, TX 78234-5081

MCCS-GPE **5 August 2003**

MEMORANDUM FOR: Executive Director, TRICARE Management Activity (TMA)

SUBJECT: Minutes of the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Executive Council Meeting

1. The DoD P&T Executive Council convened at 0800 hours on 5 August 2003 at the TRICARE Management Activity (TMA), Falls Church, VA.

2. VOTING MEMBERS PRESENT

CDR Terrance Egland, MC	DoD P& T Committee Co-chair
COL Daniel D. Remund, MS	DoD P& T Committee Co-chair
COL Joel Schmidt, MC	Army
COL Doreen Lounsbery, MC	Army
COL Mike Heath, MS (For MAJ Travis Watson, MS)	Army
LtCol Kimberly May, MC (For COL John R. Downs, MC)	Air Force
Col Bill Sykora, MC	Air Force
LtCol Phil Samples, BSC (For LtCol George Jones, BSC)	Air Force
CAPT Matt Nutaitis, MC	Navy
CDR Mark Richerson, MSC	Navy
CAPT Chuck Bruner	Coast Guard
Francine Goodman (For Mike Valentino)	Department of Veterans Affairs

VOTING MEMBERS ABSENT

None	

OTHERS PRESENT

COL William Davies, MS	DoD Pharmacy Program Director, TMA
Howard Altschwager	Deputy General Counsel, TMA
CAPT Betsy Nolan, MSC	Navy Pharmacy Specialty Leader
Col Ardis Meier, BSC	Air Force Pharmacy Consultant
MAJ John Howe, BSC	Defense Supply Center Philadelphia
CAPT Joe Torkildson, MC	DoD Pharmacoeconomic Center
CDR Denise Graham, MSC	DoD Pharmacoeconomic Center
CDR (sel) Ted Briski, MSC	DoD Pharmacoeconomic Center
LtCol Dave Bennett, BSC (via VTC)	DoD Pharmacoeconomic Center
LtCol Barb Roach, MC (via VTC)	DoD Pharmacoeconomic Center
CPT Jill Dacus, MC (Via VTC)	DoD Pharmacoeconomic Center
Shana Trice (via VTC)	DoD Pharmacoeconomic Center
Dave Bretzke (via VTC)	DoD Pharmacoeconomic Center
Angela Allerman (via VTC)	DoD Pharmacoeconomic Center
Eugene Moore (via VTC)	DoD Pharmacoeconomic Center

3. REVIEW MINUTES OF LAST MEETING

A. The Council approved the minutes of the last meeting with a correction in Table Two Section 7A: the $7.84 average monthly cost for Estraderm was based on an incorrect dosing frequency of once a week. The correct dosing frequency is twice a week, so the correct average monthly cost for Estraderm is $15.68.

B. The Council approved the minutes of the July interim "email" meeting (Appendix A) with an amendment of the thiazolidinedione (TZD) section.

4. INTERIM DECISIONS/ADMINISTRATIVE ISSUES

The July interim "email" DoD Executive Council Meeting resulted in the following BCF and TMOP changes:

- Latanoprost (Xalatan) was added to the BCF
- Rosiglitazone (Avandia) was added to the BCF
- Rosiglitazone/metformin (Avandamet) was added to the BCF
- Serevent MDI was removed from the BCF due to market withdrawal. Serevent DPI will be the remaining salmeterol on the BCF.
- Zolmitriptan oral tablets (Zomig) were added to the BCF
- Sumatriptan oral tablets (Imitrex) were removed from the BCF
- Gefitinib (Iressa) was added to the TMOP with quantity limits
- Lovastatin extended release (Altocor) was removed from the TMOP

5. NATIONAL PHARMACEUTICAL CONTRACTS AND BLANKET PURCHASE AGREEMENT (BPA) AWARDS, RENEWALS AND TERMINATIONS

A. The next option years were exercised for the following contracts: fluoxetine, indomethacin, digoxin, naproxen, ointment base, captopril, paclitaxel injection, carbidopa/levodopa SA tablets, glyburide, amantadine, buspirone, benztropine.

B. New contracts were awarded for ketoconazole cream, midazolam, pamidronate injection and zolmitriptan.

6. PROCUREMENT INITIATIVES

A. Oral Fluoroquinolones, Angiotensin Receptor Blockers (ARBs), and Bisphosphonates –CDR Briski updated the Council on the progress of the oral fluoroquinolone, ARB and bisphosphonate solicitations.

B. 2nd Generation Antihistamines – Loratadine is available to MTFs at $0.38 per dose compared to fexofenadine at $0.85 per dose and cetirizine at $0.96 per dose. Although fexofenadine currently remains on the BCF, the termination of the fexofenadine contract allows MTFs to have additional non-sedating antihistamines on their formularies. Since loratadine is significantly less expensive than all other second generation antihistamines, MTFs are encouraged to add loratadine to their formularies and maximize the use of loratadine consistent with the clinical needs of patients. [Note: The Council could not add loratadine to the BCF because over-the-counter products are generally not allowed on the BCF.] Loratadine is currently on 52% of MTF formularies.

C. Novo Insulin Products – CAPT Torkildson presented information on two issues regarding the current contract with Novo Nordisk for regular, NPH, lente, and 70/30 insulin products.

1. The Council voted at its last meeting to recommend that DSCP not exercise the final option year on the insulin contract (which covers regular, NPH, 70/30 and lente insulin), and solicit a new contract this year. This recommendation was based on the increasing utilization of both ultra-short acting insulin and alternative insulin delivery systems, neither of which is covered by the current contract. Novo approached the PEC in mid-June with a proposal to lower the FSS price on their FlexPen disposable delivery systems and continue their temporary price reduction for Novolog vials (32% reduction from the FSS price) and Novolog 70/30 vials (53% reduction from FSS) in return for a decision to exercise the final option year of the contract. Since the last meeting the PEC also received information that a third company anticipates approval of their ultra-short acting insulin product early next year.

2. Shortly after its meeting with the PEC in mid-June, Novo notified the PEC that they planned to discontinue distribution of their lente insulin product in October 2003. Novo committed to providing lente insulin to their government clients at current levels through January 2004. An analysis of PDTS data revealed that only 271 patients filled prescriptions for lente insulin at MTFs and only 63 patients filled prescriptions for lente insulin in mail order during the 2nd quarter of FY2003. The number of patient utilizing lente insulin decreased by 50% over

the previous year. Although lente insulin is covered by the current insulin contract, the discontinuation of lente insulin will affect a relatively small number of patients.

The PEC recommended that the council reverse its previous decision and instead recommend that DSCP exercise the final year of the insulin contract and delay a resolicitation of the contract until summer 2004. The Council voted unanimously to exercise the final option year of the insulin contract and defer the resolicitation of insulin contract until next summer.

7. DRUG/DRUG CLASS EVALUATIONS

A. *Oral Estropipate Hormone Replacement Therapy* – Hormone replacement therapies currently available on the BCF include oral conjugated estrogens (Premarin), oral medroxyprogesterone, combination conjugated estrogen/medroxyprogesterone (Prempro), estrogenic vaginal cream (MTFs select the brand), and estradiol transdermal systems (Esclim). The Council considered oral estropipate for addition to the BCF as an alternative oral estrogen replacement therapy.

Efficacy/Safety/Tolerability – Studies have shown that the various oral estrogen replacement products are equally efficacious in treating postmenopausal symptoms. The labeling for all oral estrogen products contains the same safety warning for the risk of heart disease, stroke, and cancer. There is no evidence that the oral estrogen products differ in tolerability.

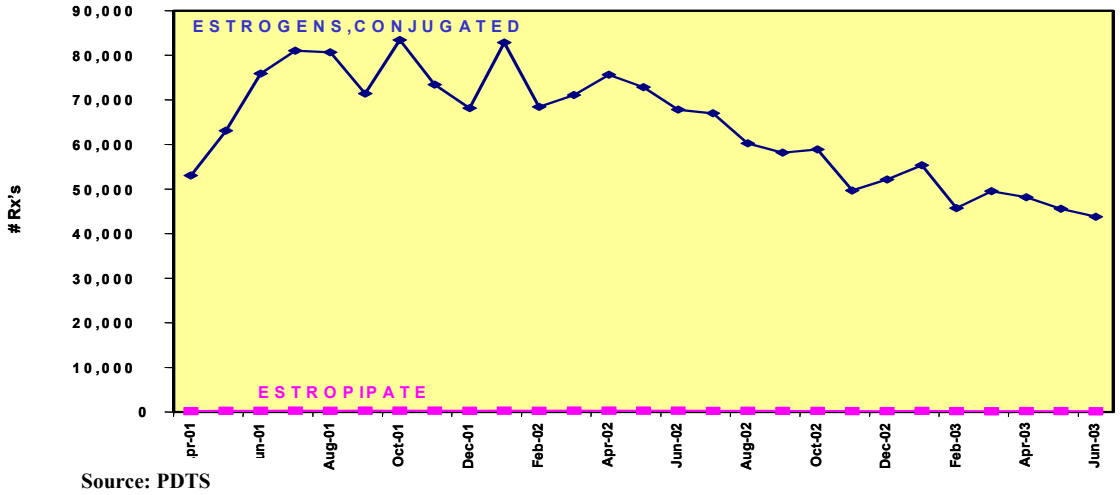
Table 1: Prime Vendor Weighted Average Cost/Tablet for Estropipate and Premarin

	Estropipate (Mylan)	**Estropipate (**Watson)	**Estropipate** (Ogen; Pharmacia & UpJohn	**Estropipate** (Ortho-est; WHFC)	**Conjugated Estrogen** (Premarin; Wyeth-Ayerst)
Prime Vendor Weighted Average Acquisition Cost/Tablet (June 2003)	$0.41	$0.11	$0.18	$0.19 (Was $0.42 prior to BPA initiated in June)	$0.23

Cost – Table 1 displays the prime vendor weighted average cost/tablet for various brands of estropipate and Premarin. Estropipate is available at a significantly lower cost than Premarin.

Other factors – The FDA and American College of Obstetricians and Gynecologists (ACOG) recommend starting women on low doses of estrogen in light of the Women's Health Initiative (WHI) study. Estropipate is not currently available in doses that are equivalent in estrogenic activity to the 0.3 mg and 0.45 mg strengths of Premarin.

Figure 1: MTF Oral Estrogen Rx Fills April 01 – June 03



Source: PDTS

Utilization – Figure 1 shows that MTFs use very little estropipate in comparison to Premarin. Only 20% of MTF formularies include estropipate compared to the 98% that include Premarin. Providers who were surveyed stated that the addition of estropipate to the BCF would not likely cause them to substantially increase their use of estropipate in lieu of Premarin.

The Council voted unanimously to not add an estropipate to the BCF because there is no evidence at this time that prescribers would be willing to use estropipate in lieu of Premarin.

B. *Dopamine Agonists* - The PEC is working with the VA on a joint review of the dopamine agonists. After the review is completed, the PEC will estimate the relative cost-effectiveness of the dopamine agonists and recommend which, if any, dopamine agonists, to add to the BCF.

C. *Isotretinoin*

Isotretinoin, a synthetic analogue of Vitamin-A, is indicated for the treatment of recalcitrant nodular acne. Available from Roche pharmaceuticals as Accutane® since 1982, isotretinoin recently became available as an AB-rated generic from three other manufacturers. The oral isotretinoin products available in the United States as of 1 July 2003 are listed in Table 2.

The Council considered an abbreviated PEC drug class review of isotretinoin for the purpose of deciding whether to pursue a sole-source contract (i.e. a contract to exclusively use a single brand of isotretinoin). Although sole-source contracts for "A-rated" generic equivalents do not typically require the review of the Council, an exception was made for isotretinoin because of its association with severe adverse events.

Table 2: Isotretinoin Products Available in the United States as of July 2003

Brand Name	Dosage Strengths	FDA approval date	Manufacturer
Accutane	10, 20, 40 mg	May 7, 1982	Hoffman – La Roche
Amnesteem	10, 20, 40 mg	Nov 15, 2002	Bertek
Sotret	10, 20, 40 mg	Dec 24, 2002	Ranbaxy labs
Claravis	10, 20, 40 mg	Apr 11, 2003	Barr

An average of 2,500 isotretinoin prescriptions are dispensed each month to DoD beneficiaries. Of these, approximately 1,500 are filled at MTFs and 1,000 through the retail network at costs of $342,000 and $221,000 respectively. The mail order system does not fill isotretinoin prescriptions because of the difficulty in meeting the requirements of the FDA mandated safety programs. The cost of a typical course of therapy for one person (15 weeks) is approximately $1,000 if the medication is dispensed through an MTF and $1,265 if the medication is dispensed through the retail network.

Efficacy/Safety – Isotretinoin has been on the market for over 20 years and remains the most efficacious treatment available for recalcitrant nodular acne. The main issue related to isotretinoin therapy is its potential to cause serious adverse effects, the most serious of which are birth defects and psychiatric disorders. In response to these adverse events, the FDA now requires that all isotretinoin therapy be administered in accordance with its strict risk management criteria.

Contracting Issues – The factors providing the impetus to pursue a sole-source contract for isotretinoin are its high cost, availability from multiple sources, and continued wide use within the MHS. The main issues to be addressed in pursuing a sole-source contract for isotretinoin include: (1) the interchangeability of the products, (2) the interchangeability of the risk management programs, and (3) the interchangeability of the prescription sticker programs.

1. Interchangeability of isotretinoin products: All four isotretinoin products available in the United States are AB-rated. By definition this means they are interchangeable.
2. Interchangeability of risk management programs: The FDA requires that the risk management programs for all isotretinoin manufacturers be the same. This is evident based on a statement by Janet Woodcock, Director of the Center for Drug Evaluation and Research, FDA that was found on the FDA web page: "All generic brands of isotretinoin will utilize the labeling that is alike in all material respects to the name brand, educational tools, and follow-up metrics in place under S.M.A.R.T." S.M.A.R.T. is the risk management program of the innovator company – Roche. To confirm this, written information included in three of the four risk management programs (SMART, SPIRIT, IMPART) were compared by members of the PEC and found to be identical in their wording. The risk management programs for each of the available products are listed in Table 3.
3. Interchangeability of prescription stickers: In a phone discussion with a Roche pharmaceutical representative regarding the interchangeability of isotretinoin

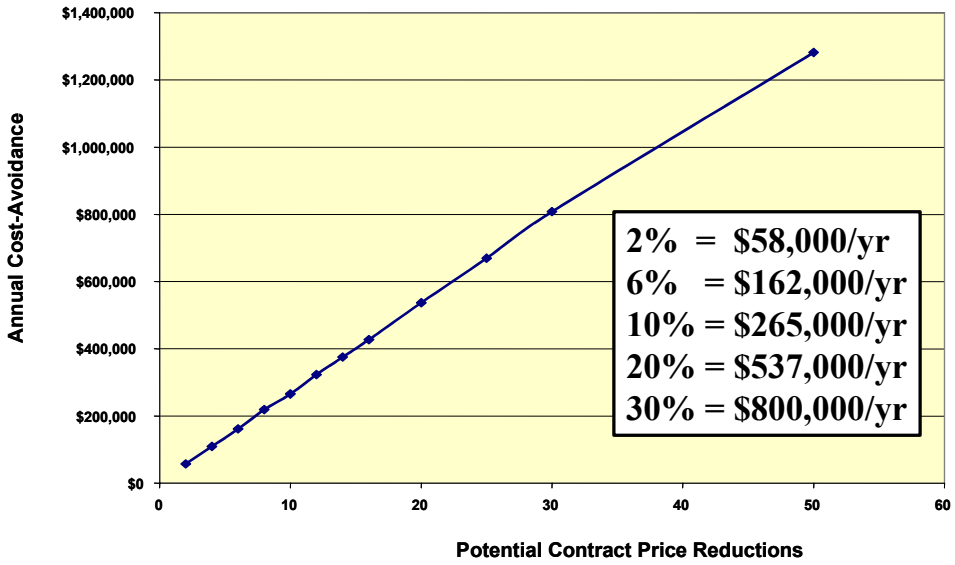
sticker programs, the following oral statement was provided: "Any AB-rated isotretinoin can be substituted for a prescription with an Accutane sticker and Accutane can be substituted for any prescription with an AB-rated isotretinoin sticker." Representatives from a state board of pharmacy (Texas) and the FDA concurred with this statement.

Table 3: Isotretinoin Risk Management Programs

Brand Name	Manufacturer	Safety Program
Accutane	Hoffman-La Roche	S.M.A.R.T. (System to manage Accutane related teratogenicity)
Amnesteem	Bertek	S.P.I.R.I.T. (System to prevent isotretinoin related issues of teratogenicity)
Sotret	Ranbaxy labs	I.M.P.A.R.T. (Isotretinoin medication program alerting you to the risks of teratogenicity)
Claravis	Barr	A.L.E.R.T. (Adverse event learning and education regarding teratogenicity)

Potential Cost-Avoidance – Figure 2 illustrates the cost-avoidance that would result from various price reductions that might be obtained with a sole-source contract for isotretinoin.

Figure 2: Isotretinoin cost avoidance from potential contract price reductions



The Council voted unanimously to support a sole-source contract initiative for isotretinoin that does not mandate addition of isotretinoin to the BCF.

8. REQUESTS FOR BCF CHANGES

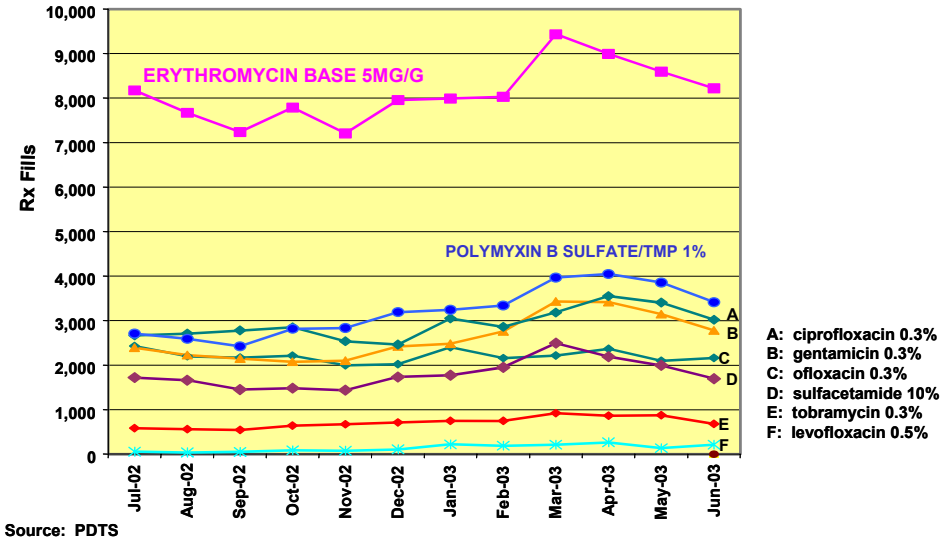
A. *Ophthalmic Antibiotics – Polymyxin B Sulfate/Trimethoprim and Erythromycin*

CDR Graham presented a recommendation from the PEC that polymyxin B sulfate/trimethoprim and erythromycin ophthalmic antibiotics be added to the BCF. This recommendation was based on two factors: 1) both are cost-effective alternatives compared to ophthalmic fluoroquinolones for primary care treatment of superficial ocular bacterial infections, including acute bacterial conjunctivitis and blepharoconjunctivitis, and 2) high utilization and formulary status in the MTFs.

Efficacy/Safety/Tolerability – Polymyxin B sulfate/trimethoprim and erythromycin have been proven efficacious in the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by susceptible organisms. Erythromycin is also safe and effective for the prophylactic treatment of ophthalmia neonatorum due to *Neisseria gonorrhoeae* or *Chlamydia trachomatis*. Safety and effectiveness of polymyxin B sulfate/trimethoprim are established down to the age of 2 months.

Cost – Both polymyxin B sulfate/trimethoprim and erythromycin are available as generics with respective costs of $1.19 – 1.52/10 ml vial and $0.99/3.5 gm tube, compared to fluoroquinolones starting around $14.00/5 ml.

Figure 3: MTF Rx Fills Ophthalmic Antibiotics July 02 – June 03



Source: PDTS

Utilization/MTF Formulary Status – Figure 3 shows current MTF utilization of polymyxin B sulfate/trimethoprim and erythromycin compared to other ophthalmic antibiotics. Over 80% of MTFs have both agents on their formulary.

The Council voted unanimously to add polymyxin B sulfate/trimethoprim ophthalmic solution and erythromycin ophthalmic ointment to the BCF.

B. *Ultra-Short Acting Insulin Products*

CAPT Torkildson and Ms. Angela Allerman presented a recommendation from the PEC that an ultra-short acting insulin product be added to the BCF. This recommendation was based on two factors: 1) the superior outcomes achieved with ultra-short acting insulin compared to regular insulin, and 2) the steadily increasing utilization of ultra-short acting insulin products in DoD.

Data were presented comparing the activity profiles of regular and ultra-short acting insulins. The more rapid onset of action, shorter time to peak activity, and shorter effective duration of action make the profile of ultra-short acting insulin more physiologic. Clinical trials demonstrate improved post-prandial glycemic control, lower HbA1c levels, and fewer episodes of post-prandial hypoglycemia with ultra-short acting insulins.

Data regarding the relative utilization of regular and ultra-short acting insulin at MTFs is presented in Table 4. The projected figures are based on the trend observed over the preceding 12 months. Based on these projections, the number of utilizers of ultra-short acting insulin products will exceed the number of regular insulin utilizers during the first quarter of FY 2004. Based on this information, the Council voted unanimously to accept the PEC's recommendation to add an ultra-short acting insulin to the BCF.

Table 4: Number of Unique Utilizers of Ultra-short Acting and Regular Insulin Products at MTFs

Quarter	Ultra-short Acting	Regular
Historical Figures		
2001, Q4	4,219	13,507
2002, Q1	4,784	13,210
2002, Q2	5,378	12,733
2002, Q3	6,055	12,289
2002, Q4	6,569	11,455
2003, Q1	7,456	11,316
2003, Q2	8,032	10,703
Projected Figures		
2003, Q3	8,638	10,248
2003, Q4	9,280	9,767
2004, Q1	9,922	9,285
2004, Q2	10,564	8,804
2004, Q3	11,206	8,322
2004, Q4	11,848	7,841

The presentation now turned to the question regarding which ultra-short acting insulin represented the most cost-effective choice for the direct care system. Data were first presented that addressed the therapeutic interchangeability, clinical coverage, and provider acceptance of Novolog and Humalog. The available data suggest no clinically relevant difference between the products' activity profiles. Although Novolog has an FDA-approved indication for use in insulin pumps and Humalog does not, several trials including a non-blinded head-to-head trial in pump patients suggest that the products are equally effective in improving post-prandial glucose control in this population. Anecdotal reports exist that suggest Novolog has greater stability and maintenance of potency in pumps, especially in warm climates, but this has not been scientifically evaluated as yet. There is no evidence for a difference in the number, type, or severity of adverse reactions seen with the two products. Therefore, either product appears to be suitable for use in diabetic patients. Either product could reasonably be expected to meet the clinical needs of the majority of patients requiring pre-prandial insulin therapy to control post-prandial hyperglycemia. Conversely, patients who failed to achieve the desired control with one of these products would be unlikely to achieve the desired control with the other.

Assessment of provider acceptance in this case was somewhat complex. As noted previously, Novo Nordisk currently has a contract to provide regular, NPH, and 70/30 mixed insulin to the DoD and VA. DoD compliance with this contract is fairly good, with about 75% of utilizers in each of these market baskets using the Novo product. However, < 3% of utilizers of ultra-short acting insulin use Novolog, despite an $8/vial cost difference in favor of Novolog. Additionally, at the time of the analysis Novolog was on formulary at only 4 MTFs throughout DoD. In a recent *PEC Update*, readers were asked to comment on why this situation existed. Responses indicated that several factors contributed to this: 1) Humalog was first to market and first on formulary (inertia); 2) providers considered the products to be clinically equivalent and were unaware of the price difference; and 3) Novolog was not on formulary at most facilities, and as the products were not seen as having substantial clinical differences providers had no motivation to push for its addition. Both junior and senior level endocrinologists expressed a willingness to change to the less expensive product, and one diabetic educator stated that she had unsuccessfully approached her local P&T Committee on three different occasions with evidence that substantial cost savings could be realized by making Novolog available to providers.

The following cost and utilization data were then presented. During the period 1 May 2002 through 30 April 2003, $3.2 million were spent on ultra-short acting insulin therapy by MTFs. Given the growing utilization of ultra-short acting insulin, it was projected that in FY 2004 MTFs would experience an 18.6% increase in the cost of ultra-short acting insulin therapy, to $3.8 million. However, given the current prices of the two products, if only 10% of the market was moved to Novolog the MTFs would experience instead a 2% decrease in the cost of therapy. If Novolog achieved a 50% market share, the overall cost would decrease by almost 15%, to $2.7 million, despite an almost 20% increase in utilization. The increase in

market share would also ensure that the Novolog prices would remain in place until the awarding of the new insulin contract next fall.

Based on these factors, the Council voted unanimously in favor of the PEC recommendation to add Novolog to the BCF, to have the PEC provide information to providers and facilities encouraging its use for the reasons noted, and to have the PEC provide additional information regarding the opportunity for facilities to achieve additional cost avoidance by evaluating the Novo FlexPen devices as an alternative to Humalog disposable syringes.

9. ADJOURNMENT

The meeting adjourned at 1400 hours. The next meeting will be held at Fort Sam Houston, TX at 0800 on Thursday, 13 November 2003. All agenda items should be submitted to the co-chairs no later than 06 October 2003.

<signed>	<signed>
DANIEL D. REMUND	TERRANCE EGLAND
COL, MS, USA	CDR, MC, USN
Co-chair	Co-chair

APPENDIX A: MINUTES OF THE DEPARTMENT OF DEFENSE (DOD) PHARMACY AND THERAPEUTICS (P&T) "EMAIL" INTERIM EXECUTIVE COUCIL MEETING

NOTE: Amended version (section 4B) approved by the DoD P&T Executive Council at their regularly scheduled meeting, 5 August 2003.

Department of Defense Pharmacoeconomic Center

2421 Dickman Rd., Bldg. 1001, Rm. 310
Fort Sam Houston, TX 78234-5081

MCCS-GPE **14 July 2003**

MEMORANDUM FOR: Executive Director, TRICARE Management Activity (TMA)

SUBJECT: Minutes of the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) "Email" Interim Executive Council Meeting

1. The DoD P&T Executive Council held an interim meeting by email on 9 July 2003 in order to make some decisions that the co-chairs felt should not be delayed until the August meeting. All voting members posted email responses by close of business 14 July 2003.

2. VOTING MEMBERS RESPONDING

CDR Terrance Egland, MC	DoD P& T Committee Co-chair
COL Daniel D. Remund, MS	DoD P& T Committee Co-chair
COL Joel Schmidt, MC	Army
COL Doreen Lounsbery, MC	Army
MAJ Travis Watson, MS	Army
COL John R. Downs, MC	Air Force
COL Bill Sykora, MC	Air Force
LtCol George Jones, BSC	Air Force
CAPT Matt Nutaitis, MC	Navy
CDR Mark Richerson, MSC	Navy
CAPT Robert Rist	Coast Guard

VOTING MEMBERS ABSTAINING

Mike Valentino	Department of Veterans Affairs

3. NATIONAL PHARMACEUTICAL CONTRACT AWARD

The VA National Acquisition Center (NAC) recently awarded a joint VA/DoD triptan contract to Astra Zeneca for zolmitriptan. Per the terms of the contract, zolmitriptan replaces sumatriptan as the only oral triptan on the BCF effective 11 Jul 03. MTFs may have one oral triptan in addition to zolmitriptan on their local formularies. The contract does not affect the formulary status of non-oral triptan dosage forms. The PEC provided guidance to MTFs for implementing the zolmitriptan contract (see the National Contracts page on the PEC website). Sumatriptan injection will remain on the BCF.

4. PROCUREMENT INITIATIVES

A. Ophthalmic Prostaglandins – At the May DoD P&T Executive Council meeting the Council was informed that the VA and DoD would each pursue their own procurement strategies for ophthalmic prostaglandins. Pfizer has proposed a blanket purchase agreement (BPA) that reduces the price of latanoprost by 25% (price decreases from $28.89 to $21.67 per bottle) if latanoprost is added to the BCF and no other ophthalmic prostaglandins are included on the BCF. Latanoprost would be the sole ophthalmic prostaglandin on the BCF, but MTFs could have additional ophthalmic prostaglandins on their local MTF formularies. The Council voted unanimously to add latanoprost to the BCF and advise DSCP to approve the latanoprost BPA.

B. Thiazolidinediones (TZDs, "Glitazones") – The Council had previously authorized the addition of a single thiazolidinedione to the BCF using a procurement strategy that could include up to a joint DoD/VA closed class contracting strategy competing rosiglitazone and pioglitazone. Glaxo Smith Kline (GSK) has proposed a joint VA/DoD BPA that offers tiered pricing for rosiglitazone (Avandia) and the combination of rosiglitazone and metformin (Avandamet) based on their aggregate market share at MTFs if Avandia and Avandamet are the only thiazolidinediones on the BCF. The Avandamet BPA price equals the rosiglitazone BPA price plus the contract price for generic metformin. The BPA pricing will provide a 20% discount to DoD based on the 68% market share that rosiglitazone currently has at MTFs. Based on historical dose distributions, the 20% discount will reduce the average daily cost for rosiglitazone from $2.16 to $1.73. The average daily cost for pioglitazone is $2.41, which is 39% more per day than rosiglitazone.

Although the Council had not previously discussed the inclusion of Avandamet in the TZD procurement strategy, the Council determined that the addition of Avandamet was consistent with previous BCF decisions and would be a rational complement to Avandia on the BCF because:

- Metformin is appropriately and frequently used in combination with rosiglitazone (50% of current rosiglitazone users are also taking metformin).
- The Council has previously concluded that combination products may be more convenient for patients to take and may improve compliance compared to giving the same products separately.
- The Avandamet pricing is cost-neutral compared to the pricing for the separate products. Although DoD currently has a contract for metformin, there have been

supply problems that cause MTFs to make off-contract purchases of metformin at higher prices. To the extent that the use of Avandamet will reduce the use of off-contract metformin, DoD will realize a cost-benefit for those patients needing combination therapy.

The Council voted unanimously to add rosiglitazone (Avandia) and the combination of rosiglitazone and metformin (Avandamet) to the BCF and advise DSCP to approve the rosiglitazone BPA.

5. BCF AND TRICARE MAIL ORDER PHARMACY (TMOP) FORMULARY ISSUES

A. Gefitinib (Iressa) 250 mg tablets – Iressa is a new oral agent approved, 5 May 03, as monotherapy for locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of both platinum-based and docetaxel (Taxotere) chemotherapies (i.e. third-line treatment).

The Council unanimously voted to not add Iressa to the BCF, but to add Iressa to the TMOP Formulary with a quantity limit of 45 tablets per 45 days, to reduce wastage. Gefitinib is costly ($1168/month based on FSS pricing) and patients are likely to discontinue therapy (2/3 of the patients receiving therapy will be treated for no longer than 3 months), either due to death or lack of response. In addition, since the symptomatic benefit of gefitinib appears to correlate with tumor response rate and occurs early in treatment, it is rational to evaluate the patient within 6 weeks (clinical investigators maintain that four to six weeks of therapy is sufficient to test for response). It also appears reasonable to discontinue therapy in patients who are not benefiting.

B Statins – At the May 03 DoD P&T Executive Council meeting the Council voted to add Altocor to the TMOP Formulary. The PEC has subsequently been advised that the addition of Altocor to the TMOP formulary may violate the provisions of the Zocor contract.

The solicitation for the new stated in part, "The BCF and Mail Order Pharmacy Formulary will also contain a generic form of lovastatin and may contain one of the HMG-CoA agents not extensively metabolized by the cytochrome P450 (CYP) metabolic pathway (i.e. pravastatin or fluvastatin), but not both."

Although the solicitation did not specifically prohibit the inclusion of a brand name version of lovastatin on the TMOP formulary, the specific reference to inclusion of a generic form of lovastatin on the TMOP formulary could reasonably be construed to imply that a brand name version of lovastatin would not be included on the TMOP formulary.

The Council voted unanimously to remove Altocor from the TMOP formulary.

6. NEXT MEETING

The next meeting will be held at TRICARE Management Activity (TMA), conference room 815, Skyline Building 6, 5111 Leesburg Pike, Falls Church, VA at 0800 on Tuesday, 5 August 2003. All agenda items should be submitted to the co-chairs no later than 18 July 2003.

<signed>	<signed>
DANIEL D. REMUND	TERRANCE EGLAND
COL, MS, USA	CDR, MC, USN
Co-chair	Co-chair