Department of Defense
Pharmacoeconomic Center

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

MCCS-GPE **13 November 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 13 November 2003 at the DoD Pharmacoeconomic Center, Fort Sam Houston, Texas.

2. VOTING MEMBERS PRESENT

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 Mark Nadeau, MC (For COL Bill Sykora, MC)	Air Force
LtCol George Jones, BSC	Air Force
CAPT Matt Nutaitis, MC	Navy
CDR Mark Richerson, MSC	Navy
CAPT Dennis Alder	Coast Guard
Kathy Kelly (For Mike Valentino)	Department of Veterans Affairs

VOTING MEMBERS ABSENT

CDR Terrance Egland, MC	DoD P& T Committee Co-chair

OTHERS PRESENT

COL William Davies, MS	DoD Pharmacy Program Director, TMA
CAPT Patricia Buss, MC	Chief Medical Officer Representative, TMA
COL Mike Heath, MS	Army Pharmacy Consultant, Chairman Pharmacy Board of Directors
LtCol Phil Samples, BSC (For Col Ardis Meier, BSC)	Air Force Pharmacy Consultant
MAJ John Howe, BSC	Defense Supply Center Philadelphia
LTC Kent Maneval, USA, MS	Joint Readiness Clinical Advisory Board
CAPT Don Nichols, MC	DoD Pharmacoeconomic Center
CDR Denise Graham, MSC	DoD Pharmacoeconomic Center
CDR Jill Pettit, MSC	DoD Pharmacoeconomic Center
CDR Ted Briski, MSC (via TC)	DoD Pharmacoeconomic Center
LtCol Dave Bennett, BSC (via TC)	DoD Pharmacoeconomic Center
LtCol Barb Roach, MC	DoD Pharmacoeconomic Center
CPT Jill Dacus, MC	DoD Pharmacoeconomic Center
Joe Torkildson, MD	DoD Pharmacoeconomic Center
Shana Trice	DoD Pharmacoeconomic Center
Dave Bretzke (via TC)	DoD Pharmacoeconomic Center
Angela Allerman	DoD Pharmacoeconomic Center
Eugene Moore	DoD Pharmacoeconomic Center
MAJ Barbara Hoeben, BSC	UT College of Pharmacy Master's Program
SFC Agustin Serrano	DoD Pharmacoeconomic Center

3. REVIEW MINUTES OF LAST MEETING

The minutes from the last meeting were accepted as written.

4. INTERIM DECISIONS/ADMINISTRATIVE ISSUES

None

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

A. The next option years were exercised for the following contracts: human insulin, and cyclobenzaprine.

B. Option years to be exercised over the next two months include the following contracts: albuterol, colchicine, permethrin, and tretinoin cream.

C. Option years not exercised due to current lower FSS prices than the contract price: rifampin, sucralfate, and salsalate.

D. DSCP signed an incentive agreement with Merck for alendronate (Fosamax) that became effective 1 October 2003. The agreement stipulates that alendronate will be the only bisphosphonate on the BCF. The class remains open on the BCF, so MTFs may have additional bisphosphonates on their formularies. The incentive agreement contains a

confidentiality clause that prohibits disclosure of the specific terms and conditions of the agreement, but it substantially reduces the price of alendronate. Estimated cost avoidance for DoD is $690,000 for the single month of October 2003.

6. PROCUREMENT INITIATIVES

A. *Oral Fluoroquinolones* – The Oral Fluoroquinolone Solicitation was posted on October 22, 2003. The solicitation offers the addition of a single oral fluoroquinolone to the Basic Core Formulary (BCF) as a workhorse agent to use in the treatment of community acquired pneumonia (CAP) and sinusitis. The solicitation closed on November 11, 2003. The award is pending.

B. *Angiotensin Receptor Blockers (ARBs)* – The ARB Solicitation was released in August 2003. The solicitation has been protested. DoD/VA is addressing the protest.

C. *Cholinesterase Inhibitors* – Two companies have offered BPAs on cholinesterase inhibitors. The Council asked the PEC to analyze the proposed BPAs and make recommendations at the next meeting.

D. *Brimonidine 0.2% Ophthalmic Solution* – The current BCF listing for brimonidine ophthalmic solution specifies the 0.15% formulation (Alphagan P). The Council placed Alphagan P on the BCF in Feb 2002 due to the planned phase-out of the 0.2% formulation by the manufacturer. The difference between the formulations is the preservative used; the 0.15% formulation (Alphagan P) contains a purite preservative, while the 0.2% formulation contains a benzylalkonium (BAK) preservative. Generic equivalents of the 0.2% formulation are now available. As part of the FDA review of generic brimonidine, the FDA determined that differences in intra-ocular pressure (IOP) lowering and adverse events between the two formulations were not clinically significant. Since generic versions of brimonidine 0.2% cost considerably less than brimonidine 0.15% (Alphagan P), the Council expressed interest in a potential sole source contract to compete generic brimonidine products for BCF addition. This issue will be reviewed at the next meeting.

7. REVIEW OF EXISTING PROCUREMENT INITIATIVES

A. *LHRH Agonists* – Goserelin Acetate Implant (AstraZeneca) was awarded a contract, effective 17 Feb 03, as the sole LHRH agonist on the BCF and VA National Formulary (VANF) for the treatment of prostate cancer. DoD has cost avoided approximately $213,000 since the contract was implemented. Goserelin acetate implants accounted for the following percentages (based on "treatment month equivalents") of LHRH agonist products purchased by MTFs during September 2003:

- DoD: 43%
- AF: 34%
- Army: 40%
- Navy: 59%

The contract reduced the price of goserelin acetate implants by 32%, which would have yielded a potential cost avoidance of $579,564 if goserelin acetate implants had accounted for 100% of the purchases. Since this class of drugs has indications other than

prostate cancer, some utilization of competing products is expected. Goserelin's market share is increasing slightly.

B. *Statins* – Simvastatin (Merck and Co) was awarded a joint VA/DoD contract, effective 1 May 03, as the sole high-potency statin on the BCF and VANF for the treatment of hyperlipidemia. MTFs may also have lovastatin and either pravastatin or fluvastatin on their formularies. DoD cost avoided approximately $31,652,000 during FY 03 within this class of drugs. The cost avoidance includes the old DoD contract and the first 3 months of the joint VA/DoD contract. Simvastatin accounted for the following percentages (based on tablets/capsules) of statins purchased by MTFs during September 2003:

- DoD: 93.4%
- AF: 95.6%
- Army: 92.8%
- Navy: 90.7%

On average, simvastatin prices are 20% less than they were under the initial DoD statin contract and 45% less than they were prior to the initial contract.

C. *Triptans* – Zolmitriptan (AstraZeneca) was awarded a contract, effective 11 July 03, as the sole 5HT1 agonist on the BCF. MTFs may have no more than one 5HT1 agonist in addition to zolmitriptan on their formularies. DoD cost avoided $701,843 during the first two months of the contract. Zolmitriptan accounted for the following percentages (based on tablets) of triptans purchased by MTFs during September 2003:

- DoD: 12%
- AF: 12%
- Army: 13%
- Navy: 11%

Zomitriptan prices are 50% less than they were before the contract. Given the large price reduction, MTFs can increase their cost avoidance by maximizing the use of zolmitriptan in lieu of other 5HT1 agonists.

D. *Nasal Steroids* – An incentive agreement for fluticasone (Flonase) nasal spray became effective 1 January 2003 and stipulated that fluticasone would be the sole aqueous nasal corticosteroid on the BCF. The class remains open on the BCF, so MTFs may have additional nasal corticosteroids on their formularies. The incentive agreement did not reduce the price of fluticasone, but it prevented an increase in price that would have occurred if MTFs had to purchase the product at the Federal Supply Schedule (FSS) price. Fluticasone nasal spray accounted for 87% of the nasal corticosteroid prescription fills at MTF pharmacies in September 2003.

E. *Proton Pump Inhibitors (PPIs)* – Rabeprazole (Aciphex) and lansoprazole (Prevacid) are the two PPIs on the BCF in accordance with the terms of incentive agreements that took effect 1 April 2003. The class remains open on the BCF, so MTFs may have additional PPIs on their formularies. Rabeprazole and lansoprazole accounted for approximately 75% and 17% respectively of PPI prescription fills at MTFs in September 2003. The weighted average cost per dose for PPIs was $0.80 in September 2003, compared to $0.40 per dose for most of calendar year 2002. The increase in cost is primarily due to a large price increase for rabeprazole. Prices for PPIs may decrease when price competition increases for generic omeprazole.

F. *Thiazolidinediones (TZDs, "Glitazones")* – Rosiglitazone (Avandia) is the only TZD on the BCF in accordance with the terms of an incentive agreement that took effect in July 2003. The class remains open on the BCF, so MTFs may have additional TZDs on their formularies. Rosiglitazone accounted for 66% of the 30-day equivalent prescriptions for TZDs at MTFs in September 2003. DoD cost avoidance for the first two months of the agreement is approximately $360,000.

G. *Second-Generation Antihistamines* – Loratadine is available to MTFs through an incentive agreement at less than half the price of other second-generation antihistamines, but loratadine accounted for only 6% of 30-day equivalent prescriptions for second-generation antihistamines at MTFs as of October 2003. The weighted average cost per dose for second-generation antihistamines at MTFs increased from $0.70 in March 2003 to $0.86 in August 2003. The Council encourages MTFs to maximize the use of loratadine (consistent with patients' clinical needs) in lieu of other second-generation antihistamines.

H. *Other Blanket Purchase Agreements (BPAs)* – The Council reviewed utilization data for ophthalmic prostaglandins, atypical antipsychotics, topical immunomodulators (TIMs), and tolterodine extended release. An estimate of the cost avoidance realized will be reported at the next meeting.

8. PHOSPHODIESTERASE-5 (PDE-5) INHIBITORS FOR ERECTILE DYSFUNCTION

In light of the recent FDA approval of a second PDE-5 inhibitor—vardenafil (Levitra)—the Health Affairs Director of Clinical Program Integration asked the DoD P&T Executive Council to review Health Affairs Policy 98-040, "Practice Guidelines for the Evaluation of Patients Requesting Sildenafil, (Viagra), for the Treatment of Male Impotence" and recommend whether the policy should be continued, modified, or rescinded. The policy mandates that sildenafil will be:

- non-formulary throughout the Military Health System (MHS)
- provided to patients only through a special order or prior authorization process
- subject to a quantity limit of six tablets per month

Based on information provided by the PEC, the Council identified the following concerns with Health Affairs Policy 98-040:

- The mandatory non-formulary status and requirement to special order or prior authorize prescriptions for sildenafil are an administrative hassle for patients, prescribers and pharmacies.
- The mandatory non-formulary status and requirement to special order or prior authorize sildenafil prescriptions inhibits the ability of MTF pharmacies to "recapture" prescription workload from the more expensive retail point of service.
- The mandatory non-formulary status precludes DoD from using formulary or procurement strategies to reduce the acquisition cost of PDE-5 inhibitors.
- One of the goals of the prior authorization process in the TMOP and retail network pharmacies is to identify patients who have psychogenic versus organic erectile

dysfunction because TRICARE does not cover the treatment of psychogenic erectile dysfunction. The prior authorization process is not meeting this goal because providers typically do not attempt to differentiate psychogenic erectile dysfunction from organic erectile dysfunction or mixed psychogenic/organic erectile dysfunction. The diagnostic tests required to confirm the diagnosis of organic erectile dysfunction are generally considered to be excessively expensive, invasive and pose unnecessary risk to the patient.

- The special order or prior authorization process is probably increasing the cost of providing erectile dysfunction therapy. In the TMOP, 27% of the prior authorization requests would have to be denied in order for DoD to break even on the cost of processing the prior authorizations versus the drug costs avoided by denying prescriptions. Over 95% of PA requests are approved in the TMOP. Unless the "sentinel effect" of the prior authorization process is large, DoD is losing money on the prior authorization process. [Note: The "sentinel effect" occurs when the requirement to obtain prior authorization causes a provider to refrain from writing a prescription for the drug.]

The Council voted to recommend that Health Affairs rescind HA Policy 98-040 and allow the DoD P&T Committee to manage the use of PDE-5 inhibitors as follows:

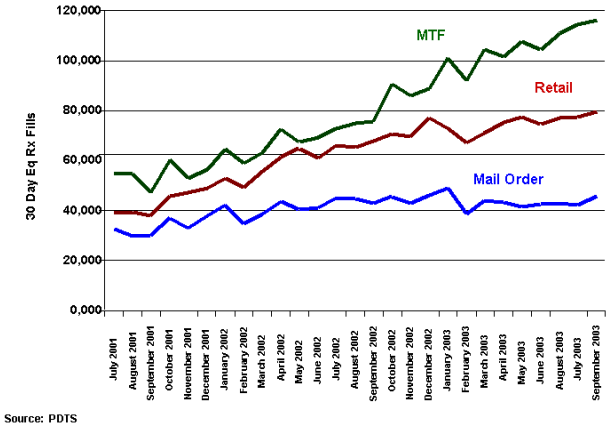
- Retain the quantity limit of six tablets per month.
- Discontinue the requirement for special order or prior authorization.
- Continue to utilize the prospective drug utilization review capabilities of CHCS and PDTS for safety monitoring.
- Consider formulary or contracting strategies to reduce the acquisition cost of PDE-5 inhibitors.

Although Health Affairs Policy 98-040 refers only to sildenafil, all PDE-5 inhibitors will be subject to the provisions of HA Policy 98-040 until Health Affairs rescinds or revises the policy.

9. DRUG/DRUG CLASS EVALUATIONS

A. Cox II Inhibitors – The Council reviewed the utilization and costs of non-steroidal anti-inflammatory drugs (NSAIDs), including the COX-2 selective NSAIDs ("COX-2 inhibitors"), in the three DoD pharmacy points of service. Utilization of COX-2 inhibitors is still increasing in MTFs and the retail network (see Figure 1 below).

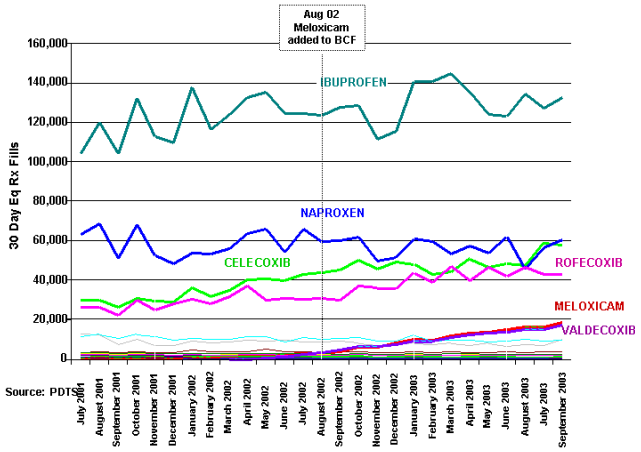
Figure 1: 30-day Equivalent Rxs for COX-2 Selective NSAIDs (Celecoxib, Rofecoxib, Valdecoxib) by Point of Service, Jul 01-Sep 03



Source: PDTS

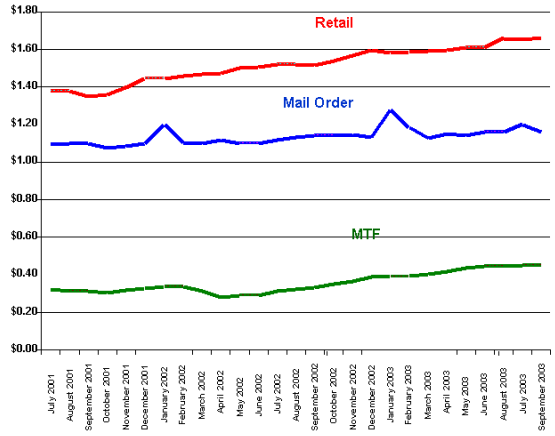
Utilization of meloxicam (Mobic; Boehringer-Ingelheim), which was added to the BCF in August 2002 as a "relatively" COX-2 selective NSAID, has increased markedly in MTFs, closely tracking utilization of the most recently approved COX-2 inhibitor, valdecoxib (Bextra; Pfizer) (see Figure 2, below). Utilization of non-selective NSAIDs (e.g., ibuprofen, naproxen) remains essentially constant.

Figure 2: MTF 30-day Equivalent Rxs for NSAIDs, Jul 01 – Sep 03



As of Sep 03, monthly costs for NSAID therapy were about $8M in the retail network, $7.5M for MTFs, and $2.5 million in mail order. The cost per unit for NSAID therapy has increased in all points of service since Jul 01 (see Figure 3, below), primarily due to increasing use of COX-2 selective NSAIDs.

Figure 3: NSAID Cost per Unit by Point of Service, Jul 01 – Sep 03



Source: PDTS

Staff members from the PEC and the VA PBM are currently working on a joint DoD/VA NSAID review to support a potential joint procurement initiative for COX-2 selective and/or relatively COX-2 selective NSAIDs.

10. REQUESTS FOR BCF CHANGES

A. *Cyclobenzaprine (Flexeril) 5 mg*

Cyclobenzaprine tablets are on the BCF. The contract price is $0.02 per 10 mg tablet. The FDA approved a new 5 mg strength of the brand name Flexeril in February 2003. The FSS price of the branded Flexeril 5 mg tablet is $0.54. Due to the high cost of the 5 mg strength, the Council clarified the BCF listing for cyclobenzaprine to exclude Flexeril 5 mg tablets.

B. *Zolmitriptan Nasal Spray*

Zolmitriptan tablets are on the BCF. Zolmitriptan nasal spray was approved in October 2003. Zolmitriptan nasal spray is not included in the current triptan contract. The FSS price of zolmitriptan 5 mg nasal spray is $15.48/dose ($92.88 per box of 6 spray devices), which is much higher than the contract price of $3.20/2.5 mg or 5 mg tablet. Due to the high cost, the Council agreed that zolmitriptan nasal spray would not be included on the BCF.

C. *Lansoprazole Oral Disintegrating Tablets and Delayed Release Suspension*

Lansoprazole capsules (Prevacid) are currently on the BCF with an incentive agreement price of $0.65/capsule. Two new formulations of lansoprazole are available, a delayed release oral suspension and an orally disintegrating tablet. The FSS prices for the suspension are $2.00/15 mg packet and $2.28/30 mg packet. The orally disintegrating tablets are $2.80/15 mg tablet and $2.85/30 mg tablet. Although these new formulations could potentially improve ease of use in pediatric and geriatric populations, the existing

capsules are approved for pediatric use in patients 1 year of age or older. They can be opened and sprinkled on soft foods or mixed with liquids and administered enterally. The delayed release suspension comes in packets that must be mixed with water and used immediately upon reconstitution. Since the suspension thickens quickly they should not be used enterally. Due to the high cost and the existence of FDA approved alternative administration options for lansoprazole capsules, the Council clarified the BCF listing for lansoprazole to exclude the oral disintegrating tablets and delayed release suspension.

D. Transdermal Scopolamine Patch

CPT Jill Dacus (PEC) presented a request from a nurse anesthetist for the addition of transdermal scopolamine patch to the BCF. The requestor's rationale was based on two considerations:

1. Transdermal scopolamine would be more cost effective than the majority of serotonin antagonists (e.g., dolasetron, granisetron, ondansetron) for prophylaxis of post-operative nausea and vomiting (PONV).

2. The potential exists for increased use of transdermal scopolamine in ambulatory surgery patients now that droperidol, formerly the most popular antiemetic for PONV, has a black box warning for QT prolongation.

Efficacy/Safety/Tolerability – Transdermal scopolamine has been proven efficacious in the prophylaxis of PONV. In a meta-analysis of 23 trials with scopolamine (N = 979) and placebo (N = 984), the relative risk for vomiting was 0.69 (95% CI 0.58-0.82), with an absolute risk reduction of 17%, and a number needed to treat (NNT) of 5.9. However, the American Society of Anesthesia Task Force on Postanesthetic Care's 2002 Practice Guidelines do not recommend scopolamine patches as first line prophylaxis, stating that the evidence for its use is less robust than for other anti-emetic agents. Scopolamine is contraindicated in children and patients with narrow angle glaucoma. Caution is advised in the elderly due to increased sensitivity to scopolamine's CNS effects, such as confusion, agitation, and hallucinations. The most common side effect is dry mouth, which occurs in 2 out of 3 patients. Administration of scopolamine for prophylaxis of PONV following ambulatory surgery is somewhat cumbersome because the patient would have to obtain the patch and apply it the evening before surgery.

Cost – The MTF average cost per dose for scopolamine is generally lower than the cost for serotonin antagonists, but is higher than the cost for other antiemetics used for PONV (e.g. promethazine). MTFs currently spend about $250K per month on serotonin antagonists, compared to $50,000 per month or less for other perioperative antiemetics.

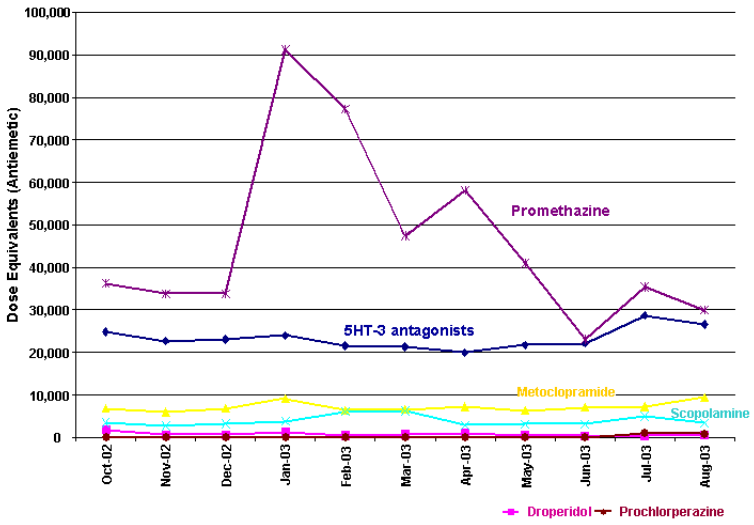
Table 1: Prime Vendor Acquisition Costs (Mean Cost per Dose, Oct 02 – Aug 03)

Antiemetic	Dosage & Route	Mean Cost per Dose
Scopolamine	1.5 mg/24 h TD placed night before surgery	$6.98*
Droperidol	1.25mg IM/IV prior to surgery	$1.63
Prochlorperazine	5-10mg IM/IV 1-2hr before surgery	$3.76-7.56
Promethazine	25-50 mg IM/IV 1-2hr before surgery	$0.05-0.16
Dolasetron	100mg PO, 12.5mg IV, within 2h start of surgery	$5.01, $24.46
Granisetron	1mg IV 30sec before anesthesia induction	$58.24
Ondansetron	16mg PO, 16mg solution PO, 4mg IV, 1hr before anesthesia	$32.46, $38.00, $11.86
Metoclopramide	10-20mg IM injection near end of surgery	$1.92-3.84

*Note: 87% of MTF purchases were for scopolamine patches in boxes of 4 at a cost of $8.59/patch; 23% of purchases were for boxes of 24 at a cost of $2.68/patch.

Utilization –MTFs purchase more dose equivalents of serotonin antagonists, promethazine and metoclopramide than they do scopolamine transdermal patches. However, purchases of scopolamine patches are higher (in terms of dose equivalents) than droperidol, which has a new black box warning, or prochlorperazine, which has not been widely available due to a national drug shortage. Table 4 shows total purchases of all of these agents, which may also be used for indications other than prophylaxis of PONV.

Figure 4: MTF Purchases of Injectable and Transdermal Antiemetics By Dose Equivalents (Oct 02 – Aug 03)



Conclusion: The Council voted unanimously not to add transdermal scopolamine to the BCF based on its high cost, low utilization, cumbersome administration requirements for PONV, and the American Society of Anesthesia Task Force on Postanesthetic Care recommendations.

E. Extended Release Morphine

Due to a lack of raw materials (opium poppy), there is a shortage of 15 mg and 30 mg strengths of MS Contin and generic morphine sulfate extended release products other than Mallincrodt's product. Mallincrodt anticipates no shortages of any strength since it is the principal supplier for all manufacturers of morphine sulfate products. The current BCF listing is for MS Contin or its generic equivalent in strengths of 15, 30, and 60 mg. Mallincrodt has an FDA-approved generic morphine sulfate extended release product that is A-B rated to MS Contin. FSS pricing for Mallinckrodt's product is less than the current FSS price for MS Contin. MTFs should be aware that the generic Mallincrodt product is currently a stable source of supply for oral morphine sulfate extended release.

11. ADJOURNMENT

The meeting adjourned at 1400 hours. The next meeting will be held at Fort Sam Houston, TX at 0800 on Wednesday, 11 February 2004. All agenda items should be submitted to the co-chairs no later than 05 January 2004.

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