Department of Defense
Pharmacoeconomic Center

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

MCCS-GPE **11 February 2004**

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 11 February 2004 at the DoD Pharmacoeconomic Center, Fort Sam Houston, Texas.

2. VOTING MEMBERS PRESENT

COL Daniel D. Remund, MS	DoD P& T Committee Co-chair
CDR Terrance Egland, MC	DoD P& T Committee Co-chair
COL Joel Schmidt, MC	Army
COL Doreen Lounsbery, MC	Army
LTC Emery Spaar, MS (For MAJ Travis Watson, MS)	Army
COL John R. Downs, MC	Air Force
Col Mark Nadeau, MC (For COL Bill Sykora, MC)	Air Force
LtCol Phil Samples, BSC	Air Force
CAPT Matt Nutaitis, MC	Navy
CDR Mark Richerson, MSC	Navy
CDR Patrick Marshall	Coast Guard
Joe Canzolino	Department of Veterans Affairs

VOTING MEMBERS ABSENT

None	

OTHERS PRESENT

COL William Davies, MS	DoD Pharmacy Program Director, TMA
CAPT Patricia Buss, MC	Deputy Chief Medical Officer Representative, TMA
Howard Altschwager	Deputy General Counsel, TMA
Paul Vasquez	Defense Supply Center Philadelphia
COL Kent Maneval, MS	Joint Readiness Clinical Advisory Board
CAPT Don Nichols, MC	DoD Pharmacoeconomic Center
CDR Denise Graham, MSC	DoD Pharmacoeconomic Center
CDR Ted Briski, MSC (via telephone)	DoD Pharmacoeconomic Center
LtCol Dave Bennett, BSC (via telephone)	DoD Pharmacoeconomic Center
LtCol Barb Roach, MC	DoD Pharmacoeconomic Center
CPT Jill Dacus, MC	DoD Pharmacoeconomic Center
SFC Agustin Serrano	DoD Pharmacoeconomic Center
Shana Trice	DoD Pharmacoeconomic Center
Dave Bretzke (via telephone)	DoD Pharmacoeconomic Center
Angela Allerman	DoD Pharmacoeconomic Center
Eugene Moore	DoD Pharmacoeconomic Center
Elizabeth Hearin	DoD Pharmacoeconomic Center
Debbie Khachikian	Department of Veterans Affairs

3. REVIEW MINUTES OF LAST MEETING

The minutes from the last meeting were accepted as written.

4. INTERIM DECISIONS/ADMINISTRATIVE ISSUES

The DoD Pharmacy and Therapeutics Executive Council held an interim meeting by email on 8 January 2004 and voted to add gatifloxacin (Tequin) to the Basic Core Formulary (BCF) and remove levofloxacin from the BCF. These BCF changes were made in response to a joint DoD/VA open class contract for gatifloxacin that became effective 15 January 2004 and in response to levofloxacin price increases. The contract designates gatifloxacin as the "workhorse" fluoroquinolone on the BCF for the indications of community acquired pneumonia and acute sinusitis at a contract price of $1.35/tablet for all oral dosage strengths. The levofloxacin 500 mg price increased from $2.01 to $5.06 on 31 January 2004. The Council concurred with the contract implementation guidance that the PEC previously issued to MTFs (www.pec.ha.osd.mil/national_contracts.htm). In light of the large price increase for levofloxacin, MTFs should remove levofloxacin from their formularies. Levofloxacin should only be used in cases of medical necessity—when gatifloxacin and other fluoroquinolones will not meet the clinical need of a patient. MTFs must rapidly decrease their use of levofloxacin in order to maximize the potential cost savings from the gatifloxacin contract.

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

A. The next option year was exercised for contracts on the following drugs: colchicine, micronized glyburide, goserelin, ibuprofen, lactulose, permethrin and verapamil.

B. The next option year was not exercised for Forest Pharmaceutical's diltiazem (Tiazac) sustained release due to availability of an AB-rated generic at $0.26 per capsule from Inwood, Forest's generic product line. The generic price became effective 15 December 2003 for the following strengths and NDCs:

Diltiazem SA 120mg Capsules	00259-3687-90	#90	$23.40
Diltiazem SA 180mg Capsules	00259-3688-90	#90	$23.40
Diltiazem SA 240mg Capsules	00259-3689-90	#90	$23.40
Diltiazem SA 300mg Capsules	00259-3690-90	#90	$23.40
Diltiazem SA 360mg Capsules	00259-3691-90	#90	$23.40

C. DSCP signed incentive agreements for Aranesp, Amgen's darbepoetin alfa, and Betaseron, Berlex's interferon beta-1b. The exact content and considerations offered in these agreements can be obtained from local Amgen or Berlex representatives or a copy can also be obtained via e-mail by directing a request to Ted.Briski@amedd.army.mil.

D. Incentive agreements are available on the DSCP website at http://dmmonline.dscp.dla.mil/pharm/incentives.asp. Incentive agreements currently apply to the products listed below. MTFs should ensure they are receiving the correct price for these products:

Alendronate (Fosamax)
Azathioprine (Imuran)
BG Strips (Precision QID, XTRA)
Celecoxib (Celebrex)
Cyclosporine (Gengraf)
Darbpoetin (Aranesp)
Dorzolamide/Timolol (Cosopt)
Estradiol (Esclim)
Estropipate (Ortho Est)
Erythropoetin (Procrit)
Fexofenadine (Allegra)
Fluticasone (Flonase)
Hepatitis A Vaccine (Havrix, Vaqta)
Hepatitis A & B Vaccine (Twinrix)
Hepatitis B Vaccine (Recombivax HB, Engerix-B)
Interferon Beta (Betaseron)
Isometheptene/APAP/Dichloralphenazone (Midrin)
Lansoprazole (Prevacid)
Latanaprost (Xalatan)
Leuprolide (Lupron)
Loratadine (Claritin)
Methylphenidate (Concerta)
Methylphenidate (Metadate CD)
Nisoldipine (Sular)
Olanzapine (Zyprexa)
Pimecrolimus (Elidel)
Phenytoin (Bertek, Mylan generic)
Quetiapine (Seroquel)
Risedronate (Actonel)
Risperidone (Risperdal)
Rizatriptan (Maxalt)
Rofecoxib (Vioxx)
Rosiglitazone (Avandia)
Tolterodine (Detrol, Detrol LA)
Travoprost (Travatan)
Valdecoxib (Bextra)
Warfarin (Coumadin)

6. BCF CHANGES AND CLARIFICATIONS

A. *Bupropion SR* – CPT Jill Dacus (PEC) presented an analysis regarding the proposed addition of bupropion sustained release (SR) to the BCF, which was suggested by the Council at the November 2003 meeting while discussing the new once-daily formulation of bupropion (Wellbutrin XL). The FDA recently approved generic equivalents to GSK's Wellbutrin SR 100 mg; generics for the 150 mg strength are expected to follow in the near future.

Efficacy/Safety/Tolerability – Bupropion SR is a dopamine-reuptake blocker indicated for the treatment of depression and, as Zyban, for smoking cessation. The comparative efficacy of bupropion SR compared to other antidepressants on the BCF is unknown. Bupropion is useful for the treatment of depression in patients who have unacceptable adverse effects, such as sexual dysfunction or weight gain, with the selective serotonin reuptake inhibitors (SSRIs) or tricyclic antidepressants (TCAs). It is not considered a first line antidepressant due to an increased incidence of seizures (about 0.1% at 100-300 mg/day, increasing to 0.4% at the maximum recommended dose of 400 mg/day). There is no evidence that the once-daily formulation of bupropion (Wellbutrin XL) differs from twice-daily bupropion SR with regard to safety or efficacy; the FDA approved both formulations based on bioequivalency studies vs. the immediate release (3 times daily) formulation.

Other Factors – Bupropion SR 100 mg and 150 mg are on 80% (143/179) and 90% (161/179) of MTF formularies, respectively, with the less-widely used 200-mg strength on only 25% of MTF formularies. As of Dec 2003, MTF prescriptions for bupropion SR totaled about 18,000 per month (14,000 for Wellbutrin SR and 4,000 for Zyban). It is unknown how many Wellbutrin SR prescriptions were prescribed for smoking cessation rather than depression. There are about 100,000 MTF prescriptions for SSRIs (the most commonly prescribed antidepressant class) each month.

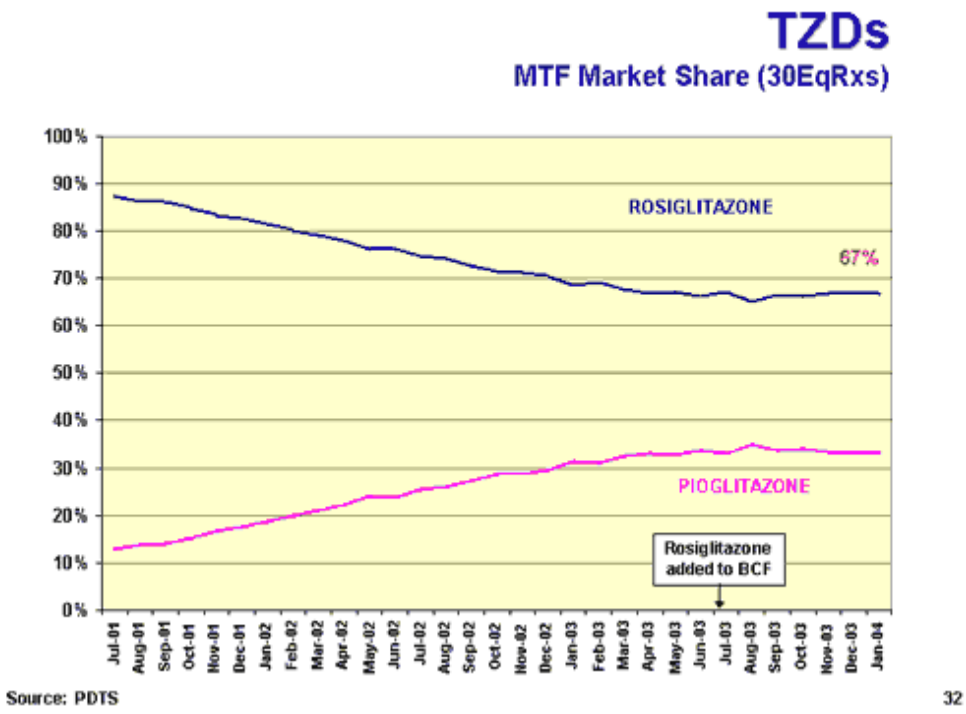
Cost – The current monthly cost for Wellbutrin SR is slightly higher than the newly introduced Wellbutrin XL ($60 vs. $58 per month, based on a typical daily dose of 300 mg). However, prices for bupropion SR should fall as generic competition increases.

The council voted unanimously to add bupropion SR 100 mg and 150 mg to the BCF based on its clinical utility in treating depressed patients who experience unacceptable adverse effects on SSRIs or TCAs, its broad representation on MTF formularies, and the increasing availability of generics. The BCF listing excludes Zyban. The presence of bupropion SR 100 mg and 150 mg on the BCF does not affect the ability of MTFs to place restrictions on the use of bupropion SR for smoking cessation if they so desire. For example, MTFs may institute and/or continue requirements that patients participate in counseling programs when bupropion SR is used for smoking cessation.

B. *Prednisolone Oral* – The BCF listing for prednisolone oral does not specify which dosage forms or strengths are on the BCF. MTF prescription data show minimal usage of prednisolone tablets. The most commonly utilized dosage form and strength is the 15 mg/5 mL syrup. The Council clarified the BCF listing for prednisolone oral to specify prednisolone 15 mg/5 mL syrup.

7. Thiazolidinediones (TZDs)

In June 2003, DoD and VA entered into an incentive agreement with GlaxoSmithKline to place rosiglitazone (Avandia), on the BCF as DoD's preferred thiazolidinedione (TZD) in exchange for a significant discount. The agreement requires that rosiglitazone maintain at least a 65% market share for DoD to achieve a substantial discount. Rosiglitazone's MTF market share had decreased from almost 90% in July 2001 to 67% in June 2003. Since the incentive agreement was implemented, rosiglitazone's market share has stabilized at 67%.



8. TRIPTANS

The zolmitriptan contract stipulates that zolmitriptan must be used for new patient starts on oral triptan therapy unless there is a medical necessity to use a different triptan. MTFs are permitted to have a second triptan on their local formulary for use by patients who have failed zolmitriptan. The contract does not mandate that patients who are already using other triptans be switched to zolmitriptan.

An analysis of prescription data for all MTFs in aggregate for December 2003 revealed that zolmitriptan was used for only 31% of new patient starts. The percentage of new patient starts for zolmitriptan varied significantly across MTFs, ranging from almost no use to as high as 81% (166/205) at Ft Bragg and 100% (22/22) at Pope AFB.

MTFs could achieve substantial cost avoidance by increasing the use of zolmitriptan for new patient starts. Zolmitriptan costs only $3.20 per dose regardless of strength. The price of other triptans depends on the formulary status at the individual MTF and any incentive agreements that may apply. However, prime vendor data for the first quarter of FY 04 show that the average cost per tablet for triptans other than zolmitriptan was $5.00. (Note: This

does not take into account the effect of rebates that an MTF may have obtained.) On average, MTFs could save $1.80 per dose by using zolmitriptan instead of other triptans.

9. CHOLINESTERASE INHIBITORS

CDR Briski presented an analysis of incentive agreements that have been proposed for donepezil (Aricept), galantamine (Reminyl) and rivastigmine (Exelon). Although the cholinesterase inhibitors have similar efficacy, donepezil is dosed once a day versus the twice daily dosing of galantamine and rivastigmine, requires fewer dosage titration steps to therapeutic dose, and appears to be better tolerated.

Donepezil accounted for 86% of the prescriptions filled at MTFs for cholinesterase inhibitors during the first quarter of FY 04. The results of a recently released clinical trial will probably help donepezil maintain or even increase its market share. The clinical trial compared donepezil in conjunction with memantine (an *N*-methyl-D-aspartate (NMDA) receptor antagonist) against donepezil plus placebo in moderate to severe Alzheimer's Disease. Patients treated with donepezil and memantine experienced significantly better outcomes than patients treated with donepezil and placebo on measures of cognition, activities of daily living, global outcome, and behavior.

Given the current and anticipated future usage trends for cholinesterase inhibitors and the pricing offered in the proposed incentive agreements, the analysis showed that DoD would obtain the greatest economic benefit by accepting the donepezil incentive agreement. The Council voted to add donepezil to the BCF and advise DSCP to accept the proposed incentive agreement for donepezil.

10. ANGIOTENSIN RECEPTOR BLOCKERS (ARBS)

A GAO protest caused the VA National Acquisition Center to withdraw the joint DoD/VA solicitation for an ARB in December 2003. The Council reviewed updated clinical information, usage data and cost data in order to formulate a DoD procurement strategy for the ARBs. The Council concluded that significant price reductions could be obtained by selecting one or more ARBs for addition to the BCF. The Council voted to have the PEC work with the Defense Supply Center Philadelphia (DCSP) to issue a BPA request for price quote for ARBs. The Council will consider the price quotes and clinical information about the ARBs to select at least one, but no more than two ARBs for addition to the BCF.

11. SECOND GENERATION ANTIHISTAMINES

The Council reviewed MTF usage and cost data for second generation antihistamines. MTF expenditures for second generation antihistamines are approaching $100 million annually. Although generic and brand name versions of loratadine are available at much lower prices than other second generation antihistamines, loratadine accounted for only 7.6% of the prescriptions for second generation antihistamines filled at MTF pharmacies during the first quarter of FY 04. Cetirizine (Zyrtec) and fexofenadine (Allegra) accounted for 47% and 45% of the prescriptions, respectively.

The Claritin brand of loratadine is available through a joint DoD/VA blanket purchase agreement for $0.38 per 10-mg tablet. Generic loratadine is available at prices as low as $0.12 per 10-mg tablet. Fexofenadine 180 mg costs $0.85 per tablet (incentive agreement

price for having fexofenadine on the BCF). The fexofenadine 180 mg price would increase to $1.42 per tablet if fexofenadine were not on the BCF. Cetirizine 10 mg costs $0.96 per tablet (Feb 2004 FSS price).

Some MTF pharmacy personnel have stated that the presence of fexofenadine on the BCF inhibits their ability to increase the use of loratadine at their MTFs. The Council considered a proposal to remove fexofenadine from the BCF. The Council was concerned that removal of fexofenadine from the BCF would not result in a large enough shift in market share to loratadine to make up for the negative financial impact of a fexofenadine price increase. The Council voted to keep fexofenadine on the BCF until there is evidence that MTFs are able to shift more usage to loratadine. The PEC will provide information to MTFs to assist them in this endeavor. The Council encourages MTFs to maximize the use of loratadine in lieu of other second generation antihistamines.

12. ADJOURNMENT

The meeting adjourned at 1400 hours. The next meeting will be held at Fort Sam Houston, TX at 0800 on Tuesday, 20 April 2004. This meeting would normally be held in May, but the meeting will be held in April in order to accommodate training of Iraqi pharmacists in formulary management procedures. All agenda items should be submitted to the co-chairs no later than 19 March 2004.

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