Department of Defense
Pharmacoeconomic Center
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Fort Sam Houston, TX 78234-6190

MCCS-GPE 13 November 1998

MEMORANDUM FOR Assistant Secretary of Defense (Health Affairs)

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

1. In accordance with the Office of the Assistant Secretary of Defense (Health Affairs) [OASD(HA)] Policy 98-025, signed 23 March 1998, a meeting of the DoD P&T committee convened at 0800 hours on 13 November 1998, at Fort Sam Houston, TX.

2. MEMBERS PRESENT:

COL William D. Strampel, MC	Co-chairman
COL Errol L. Moran, MS	Co-chairman
COL Rosa Stith, MC	US Army Representative
LTC Judith O'Connor, MC	US Army Representative
Ms. Danielle Doyle, DAC	US Army Representative
CDR Terrance Egland, MC	US Navy Representative
CDR Matt Nutaitis, MC	US Navy Representative
LCDR Denise Graham, MSC	US Navy Representative
LTC William Sykora, MC	US Air Force Representative
LtCol John R. Downs, MC	US Air Force Representative
LtCol (Sel) Greg Russie, BSC	US Air Force Representative
CDR Robert Rist	US Coast Guard Representative
Mr. John Lowe	VA Representative
LTC (P) George Crawford, MS	DMSB Representative
Capt Debra Parrish, BSC	DSCP Representative
Ms. Ray Nan Berry	Foundation Health Representative
Mr. William Hudson	Humana, Inc. Representative
Mr. Gene Lakey	TriWest Representative

3. OTHERS PRESENT:

COL Daniel Remund, MS	US Army
COL Ernest Sutton, M C	US Army

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LCDR Pamela Stewart-Kuhn	US Coast Guard
MAJ Mickey Bellemin, BSC	DSCP
LCDR Mark Richerson, MS	US Navy
Mr. Thomas Kellenberger	Merck-Medco Representative
Mr. Melvin Miller, DAC	US Army
Ms. Carol Scott, DAC	US Army
Mr. Shelby Tanner, SJA	US Army
Dr. Shana Trice, DAC	US Army

4. ISSUES DISCUSSED:

a. COL Strampel opened by stating that this will be his last meeting as co-chair since he is no longer at DoD and is now Chief of Staff for the Assistant Surgeon General of the Army at the Pentagon (1E518). At this time, no replacement has been named, however, COL Strampel stated that he would seek to get a replacement named prior to next meeting.

b. COL Moran introduced new attendees – COL Remund, PEC; MAJ Mickey Bellemi n, who will be Capt Parrish's replacement at DSCP; Mr. Thomas Kellenberger, Merck-Medco (M-M); and LTC (P) George Crawford, Defense Medical Standardization Board (DMSB). COL Moran stated that this would also be his last meeting as a member of the committee. COL Dan Remund, Deputy Director for the PEC will assume COL Moran's role as co-chair.

5. OLD BUSINESS:

a. The committee reviewed the minutes from 14 July meeting. Two changes to be made: (1) On page 5, para 6(e)(i) - change "prenatal" to "prenatal with folic acid 1mg" and change "women" to "female"; and (2) On page 6, para (9) - add weight loss and dental products (Gel-Kam and Peridex). Minutes were approved with these changes.

b. LCDR Graham commented on the last meeting minutes posted on website - Navy facilities have requested a more detailed explanation for why the committee selected/deleted certain products. The committee agreed with this request. (CLOSED)

c. Financial disclosure statements (OGE Form 450) - Mr. Tanner stated that a few members of the committee have not submitted statements. He requested that those named individuals submit such statements as soon as possible. (OPEN)

d. Alternate P&T membership: Coast Guard - LCDR Pamela Stewart-Kuhn; Air Force - LtCol Arnyce Pock and MAJ George Jones; Navy - CDR Mark Brouker and Capt Michael Fredericks; VA - Mr. Ron Moser. Army alternates not yet provided. (OPEN)

e. Fertility drugs - limitations and guidelines : Capt Parrish stated that some women were on fertility drugs for two years without results. As the cost continues to escalate for these drugs, should we continue administering to women who are infertile? COL Strampel stated that

although this is a sensitive issue, a limitation policy should be implemented. The committee recommended that this issue be forwarded to Health Affairs for consideration of establishing a DoD-wide policy. (OPEN)

f. Migraine therapy : This issue was referred to the Clinical Practice Guideline (CPG) group to consider doing a migraine treatment guideline. Their response was that they had no plans to develop a clinical practice guideline for migraine treatment and this would be better served by a PEC dispensing guideline and an educational promotional piece. COL Moran stated that he might not have satisfactorily conveyed the committee's desire to the CPG group. The committee recommended that additional communication be sent to LTC Dolter at MEDCOM, to ask the group to rethink this issue. COL Strampel said that he would also call COL Sid Adkinson on this issue. LtCol (Sel) Russie stated that if this issue is still on the table in January/February, there will be three graduate students coming to the PEC who will need a project to work on. This could be something for them to work on and gather information for guidelines. (OPEN)

g. Policy for Viagra – The policy (HA Policy 98-040) was signed by Dr. Sue Bailey on 6 August 1998. COL Strampel stated that after the policy was released he expressed several concerns about the policy to Health Affairs and sought to write an implementation plan that would clearly outline the intent of the policy. The policy contains ambiguities and questionable provisions such as:

- It appears to open up the special order process at military pharmacies to providers outside the military treatment facility, which was never the intent. The special order process is reserved only for military treatment facility providers.
- Removes Viagra from the National Mail Order Pharmacy (NMOP) formulary which would force many patients to Standard CHAMPUS at a much higher cost to DoD or would possibly cause a switch to Caverject or Muse, also at a higher cost
- Reimbursement of only six tablets per month through Standard CHAMPUS may be unenforceable.

The general counsel agreed that the policy, as written, would cause problems and COL Strampel wrote an implementation policy, which was never sent forward by Health Affairs Clinical. The Air Force has sent out their own implementation guidance and the Army Surgeon General has endorsed the HA policy. COL Moran stated that Viagra prescriptions are currently being filled at the NMOP because of the expected release of an implementation plan that would have authorized doing so. Capt Parrish stated that if Viagra were removed from the NMOP formulary, it would produce thousands of calls per month by Merck-Medco (M-M) to physicians to seek a change to more expensive agents, in which case, most physicians would probably not authorize anyway. In an effort to ensure that NMOP patients meet the HA guidelines, the PEC will develop a one-page guideline sheet which M-M will then fax to the physicians who will sign and certify that all the clinical guidelines have been met and return form within 48 hours. If not returned within that timeframe, M-M will return the prescription and inform the patient that the physician did not fill out the paperwork to have it filled. The committee recommended that COL Strampel go back to Health Affairs/TMA and seek publication of an implementation plan that would eliminate the flaws in the policy as outlined above. (OPEN)

h. NMOP antibiotic dispensing policy : CDR Egland circulated a list of antibiotics that were proposed to be exempt from the 30-day maximum quantity limitation. The committee limited the exemption for three agents (azithromycin, clarithromycin, and ciprofloxacin) to specific indications. Atovaquone and Cephalexin were deleted from the list. The committee approved the list as shown at Enclosure 1. (CLOSED)

i. Early refills - Capt Parrish s tated that M-M has implemented a procedure to handle early refill requests. Refills that are submitted early will be input into their computer, but not be filled for mail out until the due date. As an example, if a refill is due on the 14 th of the month and is sent in on the first, it will be entered and queued for mail out at the appropriate time. New prescriptions will be returned because there is no system in place to queue them for filling. Provisions have also been made for patients who call their prescription in too early. (CLOSED)

j. Oral contraceptives (21/28-day packages) - Capt Parrish stated that DSCP has asked manufacturers to reduce the prices for the 21-tablet packages to be comparable to the 28-tablet prices. Some price reductions have occurred, and some companies have not yet responded. (OPEN)

6. NEW BUSINESS:

a. **Priority Review Drugs - Automatic NMOP and Basic Core Formulary (BCF) Consideration :** None of the agents listed below were added to the BCF. Decisions regarding the NMOP preferred drug list are outlined below:

1) Rebetron® (combination of Rebetol® and Intron-A®) is currently mapped and being filled. **Add to NMOP** because it appears to offer a therapeutic advantage to interferon alone. Also **add to NMOP,** Roferon® and Infergen®.

2) Priftin® (rifapentine) - **Not added to NMOP** at this time. Wait until more usage has occurred before reconsidering. Mapped to rifampin.

3) Thalomid® (thalidomide) – **Exclusion from NMOP** due to restricted distribution requirements and mandatory testing requirements.

4) Preven® - **Exclusion from NMOP** due to time sensitivity of dosing.

5) Arava® (leflunomide) - defer decision pending evidence of usage and place in therapy. Will not be filled at NMOP at this time.

6) Sustiva® (efavirenz) – **Add to NMOP** because of indication.

7) Combivir® (lamivudine/zidovudine) – **Add to NMOP** because no more expensive than total cost of individual drugs. Committee recommended that **all oral retrovirals be added to NMOP.**

8) Xeloda® (capecitabine) – **Add to NMOP** because of indication. Committee recommended that **all oral antineoplastics be added to NMOP.**

9) Evista® (raloxifene) – **Add to NMOP** because of indication.

10) Plavix® (clopidogrel) – **Add to NMOP** because of indication and advantages to ticlopidine in aspects of dosing, monitoring requirements, and incidence of adverse effects..

11) Sulfamylon® (mafenide acetate powder) for 5% topical solution. **Not added to NMOP.** Cream is already on the NMOP. The solution has to be freshly prepared, so it is not a suitable dosage form for dispensing via the NMOP.

12) Detrol® (tolterodine) - Request from Naval Medical Center in Portsmouth to add to NMOP. Currently mapped to oxybutynin with a 20% success rate of switching. Currently, 370 patients are receiving 1mg or 2mg tablets through the NMOP. Although tolterodine has a slightly better side effect profile than oxybutynin, the committee voted to **not add to NMOP** because it is not more effective than oxybutynin and costs over four times as much.

b. **Other NMOP Issues:**

1) **Add to NMOP** – Rondec® oral drops because of listing on BCF.

2) **Add to NMOP** – Inhaler Spacers because of listing on BCF.

3) **Delete from NMOP** – Herplex® ophthalmic drops because no longer manufactured.

4) Mapping of agents by the PEC – drugs that have been mapped are: new angiotensin II receptor blocker candesartan (Atacand®) mapped to losartan, valsartan; new migraine agent rizatriptan (Maxalt® & Maxalt MLT®) mapped to sumatriptan; new SSRI citalopram (Celexa®) mapped to fluoxetine, sertraline, paroxetine; new low estrogen oral contraceptive Levlite® mapped to other oral contraceptives; mephobarbital (Mebaral®) mapped to phenobarbital; and mephenytoin (Mesantoin®) and ethotoin (Peganone®) mapped to phenytoin.

c. **BCF Issues:**

1) Non-steroidal ophthalmic agents – Fort Leavenworth requested a review of this class of drugs. Current BCF selection is flurbiprofen (Ocufen®), which lacks a primary care indication. Ketorolac (Acular®) would appear to be a more logical BCF selection because of its primary indication, however, it is more expensive than flurbiprofen. COL Moran also questioned if one is even needed for the BCF. It was suggested that local commands make their own selection. Mr. Lakey questioned the impact on the Managed Care Support contractors or inconvenience to patients. COL Strampel commented that removal of a drug from the BCF does not necessarily effect an MTF formulary because most facilities will more than likely keep an agent in this class on their local formulary. The committee removed Ocufen® from the BCF because it does not have a primary care indication that is necessary for inclusion on the BCF. The committee also did not recommend any other such agent for the BCF, preferring to let MTFs make their own choice.

2) Budesonide (Pulmicort®) and fluticasone (Flovent®) Oral Inhalers (see Enclosure 2): The committee approved the recommendation that budesonide and fluticasone oral inhalers be removed from the BCF for the reasons given in the enclosure. CDR Egland opposed removal from the BCF because his facility advocates that it is more cost effective in a subset of patients. The remaining committee members agreed that it is possible that these agents may be more cost effective for certain patients requiring high doses. However, there is insufficient evidence in the literature to strongly support this claim, and the committee does not want to mandate that facilities have a drug available at 3 to 8 times the cost of equally effective agents. Also, this decision does not prohibit individual MTFs from including these agents on their local formulary. These agents will remain on the NMOP.

3) Consider removal of specific brand designation (i.e., Coumadin® brand only) from the BCF because an AB rated generic agent is available. The primary reason the BCF listed

"Coumadin® brand (Dupont) only" is historical in nature. Back in the days of the depot system, DMSB had designated a few items as "sole source", meaning that only a designated brand could be purchased. At some point in time, Dupont brand warfarin was added as a "sole source" item. This listing carried over to the TriService Formulary (the predecessor to the BCF), then to the BCF. Also, there were not AB-rated warfarin products at that time. The first question is whether it is appropriate to have the brand name only designation on the BCF? Clinical evidence, from crossover studies, shows no difference in brand name vs. generic warfarin. Both are equally safe and efficacious according to the FDA. One initial difference is that Dupont-Merck, the maker of Coumadin®, came out with 3mg and 6mg strengths, which Barr, the maker of an AB-rated generic warfarin, did not have. However, Barr now does provide 3mg and 6mg strengths. Barr also does not currently provide the drug in unit dose packaging. Barr is anticipating providing unit dose packaging next spring. The generic tablets provided by Barr are scored, imprinted with the dosage strength, and are provided in the same color-strength combinations as the Dupont-Merck product. After discussion, the committee unanimously approved the removal of specific brand designation [i.e., Coumadin® brand (Dupont) only] from the BCF. The product will be listed on the BCF as "Warfarin oral". With this change, MTFs are now free to make their own choice as to which warfarin product is provided at their facility. The second question asked was should DoD contract for a sole source warfarin product in order to provide uniformity of product availability throughout DoD and, at the same time, generate cost savings? The committee agreed that a contract for a sole source warfarin product for DoD, either unilaterally or jointly with the VA, should be sought. COL Remund suggested that the committee make an interim special designation for dispensing warfarin through the NMOP to avoid potentially switching patients from the brand name to the generic and back to the brand name (depending on which agent is selected for the contract). The special designation would be that switching NMOP patients to generic warfarin would be held in abeyance until the contracting issue is completed. No calls will be made on prescriptions for Coumadin® , they will be filled as written. If a prescription comes in as "warfarin" or "substitution allowed", then the prescription can be filled with generic warfarin. The committee agreed. (CLOSED)

4) Long-acting nifedipine: Currently, the BCF states that all facilities must have a long-acting nifedipine on their formulary, the choices being either Adalat CC® or Procardia XL®. An MTF may have both on their formulary , however, they are not required to have both. COL Remund suggested that the PEC and DSCP go out for a blanket purchase agreement to identify the single form of nifedipine extended release that would be placed on the BCF without the closing the class. This would allow flexibility for MTFs who want both drugs and it would also achieve uniformity and possibly lower prices. Currently, the DAPA prices for Adalat CC® are $0.46 per tablet for all strengths (30mg, 60mg, & 90mg). DAPA per tablet prices for Procardia XL® are $0.65 for 30mg, $1.18 for 60mg, & $1.20 for 90mg. Since the VA has selected Adalat CC® as their preferred long-acting nifedipine and current prices favor Adalat CC®, COL Strampel recommended that the following be listed on the BCF: "Long-acting nifedipine (Adalat CC®) – class remains open. MTFs must have Adalat CC® on their formulary, but may choose to also have Procardia XL®". Again, this will help to establish uniformity across DoD, yet, allow MTFs to also add Procardia XL® if they so desire. The committee agreed. The committee also agreed that only Adalat CC® should be listed on the NMOP. Procardia XL® will be removed from the NMOP Preferred Drug List. (CLOSED)

5) Angiotensin II Receptors - should one be included on the BCF? The committee does not support adding such an agent to the BCF because most patients can be successfully treated with an ACE inhibitor. Should DSCP seek BPAs with the manufacturers in an effort to obtain lower prices? The committee supported this strategy , however, one will not be placed on the BCF. (OPEN)

d. **Contracting Issues:**

1) Non-sedating antihistamines – seek price reductions through BPAs, but not for the purpose of putting one on the BCF. Motion passed. (OPEN)

2) Selective Serotonin Reuptake Inhibitors (SSRIs) – COL Sutton stated that the proposed strategy is to select one SSRI for placement on the BCF and NMOP. The SSRI class would remain open on the BCF and the NMOP. This strategy would ensure uniform availability of one SSRI throughout DoD. Local P&T committees could add additional SSRIs to their formularies as necessary to meet the clinical needs of patients and the preferences of MTF providers. The committee approved the proposed contracting strategy and five of the six proposed evaluation factors as presented by Mr. Miller. These evaluation factors may be contract sensitive, therefore, specific details are not provided in these minutes. (OPEN)

3) Proton Pump Inhibitors (PPIs) – COL Sutton stated that the proposed strategy is to seek a sole source contract through DPSC to select one PPI, either omeprazole (Prilosec®) or lansoprazole (Prevacid®), for the BCF and NMOP. The PPI class would be closed. This means that the selected agent will be the only PPI that will be dispensed through the NMOP and at MTFs. MTFs would still be able to utilize a local special order process for patients not successfully treated with the selected agent. Managed Care Support contractors would use the prior authorization process for prescriptions that are for the agent not selected. The NMOP contract does not allow for the prior authorization process, therefore, only the selected agent will be dispensed through the NMOP. The committee approved the strategy. (OPEN)

4) Glucose Test Strips – LtCol (Sel) Russie stated that the proposed strategy is to seek a sole source contract through DPSC to select one glucose test strip for the BCF and NMOP, with the class being closed. Five companies have made pre-solicitation presentations. The committee approved the proposed contracting strategy and the evaluation factors as presented by LtCol (Sel) Russie. These evaluation factors may be contract sensitive, therefore, specific details are not provided in these minutes. Target date for issuing the solicitation is January/February timeframe. (OPEN)

5) Fluoroquinolones – Does the committee think it's reasonable to have a fluoroquinolone on the BCF? One concern raised by LtCol (Sel) Russie was do we really want to mandate a fluoroquinolone on small facilities or clinics? The committee members agreed that every facility should have a fluoroquinolone on their formulary. A notation will be place on the BCF that will indicate that each facility must have a fluoroquinolone on their formulary. A specific fluoroquinolone will not be selected unless a clear choice can be made due to voluntary price reductions. Until a BCF selection is made, individual facilities will make their own choice as to which fluoroquinolone is carried on their formulary. (OPEN)

e. Other Issues:

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1) Palivizumab (Synagis®) - Do we need prescribing guidelines for this agent? One issue is that some MTFs are/were sending patients downtown to obtain the drug and brought back to the hospital for administration. TriWest has had numerous communications with TMA to get this issue resolved, without success. COL Strampel will discuss this issue with the medical director of TMA. COL Strampel stated that it should be emphasized that if the hospital has responsibility for the primary care of the patient, they should be taking care of them and not sending them out. If the hospital does not have the capability for such treatment, which is unlikely, then, they should terminate their care and turn the patient over to the contractor. If the hospital is already providing the care, it is their responsibility to obtain the drug for the patient. Dr. Egland provided the committee with criteria for use of Synagis® and Respigam® that are being used at Naval Medical Center, Portsmouth, VA. LtCol (Sel) Russie recommended that these guidelines be attached to the minutes of this meeting to serve as a guide for developing local guidelines. The committee approved this recommendation (see Enclosure 3). (CLOSED)

2) Status of statins contract - COL Remund stated that DSCP issued the statin solicitation on 23 Oct 98. Offers are due on 23 Nov 98. The solicitation was issued without a final review by the PEC. DSCP is working on an amendment to correct various errors and modify certain clauses in the solicitation. DSCP may decide to extend the due date for offers. COL Remund reiterated the strategy that was approved at the last P&T meeting – the class will be closed and a minimum of one, maximum of two statins will be selected for the BCF and NMOP. Either atorvastatin or simvastatin will be selected in order to meet the needs of patients requiring large reductions in LDL-C. A contract will be established for a second statin if the addition of the second statin to the BCF and NMOP is predicted to be more cost-efficacious than atorvastatin or simvastatin alone. (OPEN)

3) Request that quantity limitations which are in effect at the NMOP be equally applied to prescriptions filled by the TRICARE contractors. The committee position was that an appeal be made to TMA to allow this. COL Strampel stated that this was an issue going back to HA to ask if they will write a policy to do this as a first step. (OPEN)

4) COL Strampel raised the issue of flu shots for all the children in the world. Will this raise any problems or impact us? May become a bigger issue by next year. Put on the agenda for next meeting. (OPEN)

5) Capt Parrish raised one issue of a letter she received from TMA concerning non FDA-approved indications for some odd things such as Nizoral® for prostate cancer, Clomid® for men, tamoxifen for brain cancer, etc. COL Moran stated that current rules allow for filling of prescriptions for off-label use if there is literature substantiating such use. TMA said they would pay for it under standard CHAMPUS although CHAMPUS does not set forth who conducts the medical review and who makes the ultimate decision. The rules aren't very clear. The decision for the committee may be that because of the limited number of patients in this situation it would be beyond the scope of the NMOP to deal with. Therefore, prescriptions for off-label indications would not be filled by the NMOP, on a routine basis. (CLOSED)

7. ADJOURNMENT:

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The meeting adjourned at 1215 hours. Location and date of next meeting has been set for 5 February 1999, 0800 hrs, at Health Affairs in Skyline Five. This will coincide with the TRICARE meeting, 1-5 Feb, in Washington, DC.

Enclosures

ERROL L. MORAN
COL, MS
Co-chairman

WILLIAM D. STRAMPEL
COL, MC
Co-chairman

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Summary of BCF Changes

1. **Additions:**
   Nifedipine long-acting (Adalat CC®) (see pg 6-7)
2. **Deletions:**
   Budesonide (Pulmicort®) (see pg 5-6)
   Flurbiprofen (Ocufen®) (see pg 5)
   Fluticasone (Flovent®) (see pg 5-6)
   Nifedipine long-acting (Procardia XL®) (see pg 6-7)
3. **Other changes/notes:**
   Removal of "Coumadin® brand (Dupont) only" notation for Warfarin (see pg 6)
   Removal of notation that MTFs must have one long-acting nifedipine. The long-acting nifedipine of choice is Adalat CC® (see pg 6-7)

Summary of NMOP Changes

1. **Additions:**
   Combivir® (see pg 4)
   Evista® (see pg 4)
   Infergen® (see pg 4)
   Inhaler spacers (see pg 5)
   Plavix® (see pg 5)
   Rebetron® (see pg 4)
   Roferon® (see pg 4)
   Rondec oral drops (see pg 5)
   Sustiva® (see pg 4)
   Xeloda® (see pg 4)
2. **Deletions:**
   Herplex® ophthalmic drops (see pg 5)
   Procardia XL® (see pg 6-7)
3. **Exclusions:**
   Preven® (see pg 4)
   Thalidomide (Thalomid®) (see pg 4)
4. **Other changes/notes:**
   Approved list of antibiotics exempt from 30-day maximum quantity limitation (see pg 4)
   Merck-Medco implemented procedure for handling early refill requests (see pg 4)
   In future, all oral antineoplastics and oral retrovirals will be added automatically (see pg 4)
   Some price reductions obtained on 21-day oral contraceptives (see pg 4)
   Removal of Coumadin® brand only – patients not to be switched to generic, yet (see pg 6)

8:00 ANTI-INFECTIVE AGENTS EXEMPT FROM THE NMOP 30 DAY TREATMENT LIMIT

AHFS Classification	Anti-Infective Agent	FDA Indication	Non-FDA Indication	Comments
8:04 Amebicides (none – tx <20 days)				
8:08 Anthelmintics (none – tx is 30 days or less)				
8:12 Antibiotics				
8:12.04 Antifungal				
8:12.04 (addition)	Fluconazole (Diflucan®)	Cryptococal, thrush prophylaxis & coccidiomycoci		
8:12.04	Flucytosine (Ancobon®)	Candida or Cryptococcus septicemias & UTI	Chromomycosis	
8:12.04	Griseofulvin (Fulvicin®, etc)	Ringworm infections		
8:12.04	Itraconazole (Sporanox®)	Blastomycosis, Histoplasmosis, Aspergillosis, Onychomycosis	Dermatophytoses, Pityriasis versicolor, Sebopsoriasis, Candidiasis	
8:12.04	Ketoconazole (Nizoral®)	Systemic funal infections	Onychomycosis, pityriasis versicolor, tinea pedis, corporis and cruuris, tinea capitis and vaginal candidiasis; advanced prostate ca; cushing's syndrome	
8:12.04	Nystatin (Mycostatin®, Nilstat®)	Candidiasis		
8:12.04 (addition)	Terbinafine (Lamisil®)	Onchomycosis		
8:12.06 Cephalosporins (deletion)				
8:12.06 (deletion)	Cephalexin (Kelfex®)		UTI Prophylaxis and osteomyelitis	
8:12.12 Macrolides				
8:12.12 (addition)	Erythromycin	Acne		
8:12.12 (addition)	Azithromycin	Mycobacterium avium Complex		**Over 30 days only for listed indication(s)**
8:12.12 (addition)	Clarithromycin	MAC		**Over 30 days only for listed indication(s)**
8:12.16 Penicillins				
8:12.16 (addition)	Penicillin V K or Penicillin G	Prophylaxis of Pneumococcal Infections and recurrent rheumatic fever	SS dx	
8:12.16 (addition)	Amoxicillin (Amoxil®)	Chronic UTI tx.		

AHFS Classification	Anti-Infective Agent	FDA Indication	Non-FDA Indication	Comments
8:12.24 Tetracyclines				
8:12.24 (addition)	Doxycycline (Vibramycin®)	Chemoprophylaxis of malaria		
8:12.24	Minocycline (Minocin®)	Inflammatory acne, Nocardiosis		
8:12.24	Tetracycline (Sumycin®)	Inflammatory Acne, H. Pylori, actinomycosis		
8:12.28 Miscellanous				
8:12.28 (addition)	Clindamycin (Cleocin®)	Toxoplasmosis, acne vulgaris		
8:16 Antituberculosis Agents				
8:16 (addition)	P-Aminosalicylic Acid (Sodium P.A.S®)	Retreatment of TB		
8:16 (addition)	Cycloserine (Seromycin®)	Active pulmonary & extrapulmonary TB		
8:16	Ethambutol (Myambutol®)	Primary agent in tx of TB		
8:16	Ethionamide (Trecator-SC®)	Treatment of TB when first line fails		
8:16	Isoniazid	Primary tx of TB		
8:16	Rifamate® - 150 mg INH with 300 mg Rifampin	Primary tx of TB		
8:16	Rifater® - 50 mg INH with Pyrazinamide 300 mg and Rifampin 120 mg	Primary tx of TB		
8:16	Pyrazinamide	Primary tx of TB		
8:16	Ribabutim (Mycobutin®)	Prevention of disseminated MAC		
8:16	Rifampin (Rifadin®)	Primary tx of TB		
8:18 Antivials				
8:18	Acyclovir (Zovirax®)	Chronic suppresssive tx of genital herpes		
8:18	Amantadine (Symmetrel®)	Influenza A Chemoprophylaxis		
8:18 (addition)	Famciclovir (Famvir®)	Suppression of genital herpes		
8:18	Ganciclovir (Cytovene®)	Prevention of CMV in HIV pts		
8:18 (addition)	Rimantadine	Prophylaxis of		

	(Flumadine®)	various strains of influenza A		

AHFS Classification	Anti-Infective Agent	FDA Indication	Non-FDA Indication	Comments
8:18.08 Antiretroviral Agents (all agents in class such as those listed here as new additions to class)				
8:18.08	Delaviridine Mesylate (Rescriptor®)	HIV Infection		
8:18.08	Didanosine (Videx®)	HIV Infection		
8:18.08	Indinavir (Crixivan®)	HIV Infection		
8:18.08	Lamivudine (Epivir®)	HIV Infection		
8:18.08 (addition)	Lamivudine/ Zidovudine (Combivir®)	HIV Infection		
8:18.08	Nelfinavir Mesylate (Viracept®)	HIV Infection		
8:18.08	Nevirapine (Viramune®)	HIV Infection		
8:18.08	Ritonavir (Novir®)	HIV Infection		
8:18.08	Saquinavir (Invirase®)	HIV Infection		
8:18.08	Stavudine (Zerit®)	HIV Infection		
8:18.08	Zalcitabine (Hivid®)	HIV Infection		
8:18.08	Zidovudine (Retrovir®)	HIV Infection		
8:20 Antimalarial Agents				
8:20	Chloroquine (Aralen®)	Malaria prophylaxis		
8:20	Hydroxychloroquine (Plaquenil®)	Malaria, lupus erythematous, rheumatoid arthiritis		
8:20	Mefloquine (Lariam®)	Malaria prophylaxis		
8:20	Pyrimethamine (Daraprim®)	Chemoprophylaxis of malaria, Toxoplasmosis		
8:20	Pyrimethamine/ Sulfadiazine (Fansidar®)	Malaria, toxoplasmosis		
8:20 (addition)	Doxycycline	Malaria Prophylaxis		
8:22 Quinolones				
8:22 (addition)	Ciprofloxacin (Cipro®)	Osteomeylitis, prostatitis, Mycobacterial Inf		**Over 30 days only for listed indication(s)**
8:24 Sulfonamides				
8:24 (addition)	Sulfadiazine	Toxoplasmosis in HIV , Nocardiosis, Prophylaxis of		

		Recurrent Rheumatic fever		
8:24	Sulfasalazine (Azulfidine®)	Ulcerative colitis		

AHFS Classification	Anti-Infective Agent	FDA Indication	Non-FDA Indication	Comments
8:26 Sulfones				
8:26	Dapsone	Leprosy, Dermatitis Herpetiformis, Malaria, PCP		
8:36 Urinary Anti- Infectives				
8:36 (addition)	Methenamine (Hiprex®, Urex®)	Prophylaxis of recurrent UTI		
8:36 (addition)	Nitrofurantoin (Macrodantin®)	Prophylaxis of recurrent UTI		
8:36 (addition)	Trimethoprim (Trimpex®)	Suppression of recurrent UTI, PCP		
8:40 Miscellaneous Anti- Infectives				
8:40 (deletion)	Atovaquone (Mepron®)	Pneumocystits carinii		750 mg bid for 21 days therefore <30 days.
8:40	Clofazimine (Lamprene®)	Leprosy	Tx of MAC, mycobatcterial infections	
8:40 (addition)	Co-trimoxazole	PCP prophylaxis, Nocardia, pneumonic plaque,, toxoplasmosis prophylaxis		

Budesonide and Fluticasone

1. Objective

a. Should Pulmicort Turbuhaler® (budesonide) and Flovent® (fluticasone) be retained on the Basic Core Formulary?

2. Cost Comparison Chart

Drug	Equivalent Puffs	Cost of Equivalent Puffs
Triamcinolone	4	$0.12
Flunisolide	4	$0.12
Beclomethasone 42 mcg	2	$0.04
Beclomethasone 84 mcg	1	$0.04
Fluticasone 44 mcg	4	$0.44
Fluticasone 110 mcg	2	$0.36
Fluticasone 220 mcg	1	$0.35
Budesonide 100 mcg	1	$0.33

3. Areas Where Evidence Is Sufficient

a. Clinical trials suggest that pulmicort and fluticasone are equally efficacious compared to other oral inhaled corticosteroids when used in equipotent doses.

b. Clinical trials suggest that use of higher potency corticosteroid inhalers results in patients being maintained on fewer puffs per day, possibly enhancing compliance.

c. Some patients may find benefit in using an inhaler that delivers an effective dose with fewer puffs per day.

d. Some patients may find budesonide's dry powder inhaler/delivery device easier to use than inhalers requiring coordination of a spacer device.

4. Areas Where Evidence Is Lacking

a. The PEC's selection of fluticasone and budesonide for inclusion on the BCF was based on an analysis of the effect of steroid inhaler usage on total costs (i.e. admissions, emergency department visits, lost productivity). However, this analysis may have overestimated the effect of multi-puff administration on regimen compliance.

b. There is no evidence in the literature that directly correlates the prescribed number of puffs per administration with adherence to the prescribed regimen.

c. There is no evidence in the literature that the benefits of fluticasone and budesonide (fewer puffs per day, increased compliance, and ease of use) directly produce a quantifiable, statistically significant difference in clinical outcomes (admissions, E.D. visits, symptom free days) of asthma care.

4. Recommendation:

The DOD PEC recommends that Pulmicort (budesonide) and Flovent (fluticasone) be removed from the BCF for the following reasons:

1. Lack of quantifiable evidence in the literature that the benefits of these drugs directly influence the clinical outcomes of asthma significantly more than their lower potency comparator drugs.

2. Possibility that the PEC's earlier analysis of asthma corticosteroid therapy may have overestimated the effect of potentially improved compliance on the overall cost of asthma therapy.

Eugene Moore, PharmD
DOD Pharmacoeconomic Center

Criteria for Use of Synagis® and Respigam® To Select Infant Patients*

1. For use with the approval of a staff neonatologist, pediatric pulmonologist, or pediatric cardiologist between the months of November and April.

2. Infants born at or less than 28 weeks gestational age, with or without the diagnosis of Chronic Lung Disease (CLD), and less than 12 months corrected age.

3. Infants born between 29 and up to 32 weeks gestational age with the diagnosis of CLD and less than 12 months corrected age.

4. Infants born between 29 and up to 32 weeks gestational age without the diagnosis of CLD and less than 6 months of corrected age.

5. Premature infants born at greater than 32 weeks gestation, discharged between November and March, will be considered on a case by case basis. Consideration will be given to severity of lung disease, need for supplemental oxygen and pulmonary medications.

6. Infants in the NICU at highest risk for severe RSV morbidity, potentially exposed to an index case of RSV in the NICU.

7. Patients with a diagnosis of CLD and less than two years of age who have received oxygen or medications (steroids, diuretics) for CLD within the past 6 months.

8. Infants with congenital heart disease will be considered on a case by case basis by a neonatologist or pediatric cardiologist.

9. Infants with cystic fibrosis, other forms of chronic lung disease, or pulmonary hypoplasia, will be considered on a case by case basis by a neonatologist or pediatric pulmonologist.

***** These criteria were prepared for use at Naval Medical Center, Portsmouth, VA, and is intended as a guide for use by medical treatment facilities within DoD

Department of Defense

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MCCS-GPE 14 July 1998

MEMORANDUM FOR Assistant Secretary of Defense (Health Affairs)

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

1. In accordance with the Office of the Assistant Secretary of Defense (Health Affairs) [OASD(HA)] Policy 98-025, signed 23 March 1998, a meeting of the DoD P&T committee convened on 13-14 July 1998, at Fort Sam Houston, TX.

2. MEMBERS PRESENT:

COL William D. Strampel, MC	Co-chairman
COL Errol L. Moran, MS	Co-chairman
COL Rosa Stith, MC	US Army Representative
LTC Judith O'Connor, MC	US Army Representative
Ms. Danielle Doyle, DAC	US Army Representative
CDR Terrance Egland, MC	US Navy Representative
CDR Matt Nutaitis, MC	US Navy Representative
LCDR Denise Graham, MSC	US Navy Representative
LTC William Sykora, MC	US Air Force Representative
LtCol John R. Downs, MC	US Air Force Representative
MAJ Greg Russie, BSC	US Air Force Representative
CDR Robert Rist	US Coast Guard Representative
Mr. John Lowe	VA Representative
LtCol Wayne Cheatum, BSC	DMSB Representative
Capt Debra Parrish, BSC	DSCP Representative
Ms. Ray Nan Berry	Foundation Health Representative
Mr. William Hudson	Humana, Inc. Representative
Mr. Gene Lakey	TriWest Representative

3. OTHERS PRESENT:

CAPT Chuck Bruner	USCG
COL Patricia Hobbs, BSC	USAF

COL James Normark, BSC	USAF
COL Ernest Sutton, MC	USA
COL Roger F. Williams, MS	USA
Mr. Shelby Tanner, SJA	USA

4. ISSUES DISCUSSED:

a. P&T Committee members introduced themselves and gave a background review of their experience. COL Moran introduced the members of the DoD Pharmacy Board of Directors, managed care support contractors, and other attendees.

b. MAJ Russie gave a presentation on the global perspective of formulary management and an overview of the drug distribution systems within DoD.

c. COL Moran provided the committee with a background review of how and why this committee was formed and the role of the PEC.

d. Mr. Shelby Tanner explained the need for each member to fill out an OGE 450 form (Financial Disclosure Statement). Each member is required to fax a copy of this form to the PEC by next meeting date.

e. Selection of physician co-chair: COL Strampel, as a representative of TRICARE Management Activity, will serve as co-chair.

f. Meeting schedules, locations and meeting process: The next P&T committee meeting will be held 13 November 1998, in conjunction with the AMSUS meeting, in San Antonio, TX. Exact location to be determined. Subsequent meetings will be scheduled at each future meeting. The committee will request through the appropriate commands that an alternate representative be nominated for each member in the event the primary member is unable to make a meeting. The uniform for meetings will be casual civilian attire. Discussions will be limited to agenda items, unless there is a pressing issue. Submissions of topics for inclusion on the agenda should be submitted as soon as possible. The deadline for items to be included on the agenda is 30 days prior to meeting.

g. Policies/procedures regarding communication and interaction between pharmaceutical representatives and DoD P&T committee members: All communication, dealing with P&T issues, are to be routed through the PEC. COL Moran will assign a PEC staff member (non-P&T member) as a liaison. Individual members will determine to what extent they will interact with pharmaceutical representatives at their facility.

h. CDR Egland questioned who was the approval authority for P&T issues and meeting minutes. COL Moran responded that, as per the policy that established this committee, the P&T committee is the final approving authority for any and all changes to the BCF/NMOP and the meeting minutes, which will be posted to the PEC web page.

i. Policies/procedures for including/excluding/deleting products on the BCF/NMOP and Special Purchase Request Data Sheet: All Medical Treatment Facilities (MTFs) may submit requests for changes to the DoD P&T committee. Such requests must be recommended by the MTF P&T committee and approved by the MTF commander and must provide all information as required by Appendix A of the policy that established the DoD P&T committee. All MTFs will be notified of this requirement. The special purchase data sheet (Appendix B of the DoD P&T policy) will not come into effect until therapeutic classes are closed. Patient care will be the main focus as opposed to saving money.

j. Mechanism for interim changes: When an issue arises that requires timely action, COL Moran will call together a subgroup of the membership to develop a decision, which will then be communicated to all members for a consensus. This process will be accomplished within 48 hours. Such actions will be formally approved at the next scheduled meeting. In order to facilitate this process, COL Moran requested that each member inform him of all leaves or absences.

k. Treatment guidelines development: COL Moran informed the membership that DoD and VA are working together to develop treatment guidelines for specific diseases. The current joint effort includes: Tier 1: smoking cessation, hypertension, and lower back pain; Tier 2: reactive airway diseases, hyperlipidemia, AMI, and diabetes; Tier 3: depression/suicide prevention. A PEC member is involved in each of the workgroups. Decisions by these workgroups may affect decisions this P&T committee makes and vice versa.

l. Contracting Issues:

(1) Joint ventures with the VA:

(a) A Federal Pharmacy Executive Steering Committee (FPESC) was formed which will meet in August 1998 to identify classes of drugs suitable for joint contracting efforts. Both co-chairs of the DoD P&T committee are members of the FPESC.

(b) There currently are several contracting initiatives ongoing. These include: long-acting diltiazem, generic albuterol inhaler, generic cimetidine and ranitidine, and the SSRI class of drugs.

(2) Strategies and technical evaluation factors for product selection: DoD very much wanted to join with the VA in contracting for one or more HMG-CoA reductase inhibitors (statins), however, the VA unilaterally decided to continue with their current contract for lovastatin and simvastatin. Therefore, DoD (PEC and the Board of Pharmacy) decided to pursue a separate contract. COL Moran explained the proposed contracting strategy. He also explained the technical evaluation factors that the PEC is proposing for selecting the agent(s). The committee approved, unanimously, both the strategy and the technical evaluation factors.

(3) Categories for future contracting: COL Moran explained that efforts to pursue contracts are generally based on high-dollar, high-volume agents or drug classes. As such, the following list of drugs/classes were considered for contracting initiatives: Proton pump inhibitors, ACE inhibitors, long-acting nifedipine, and glucose test strips. The committee approved pursuing contracting initiatives for these, whether jointly with the VA, or unilaterally through the Defense Supply Center Philadelphia (DSCP). The decision to pursue joint contracts will be made by the

FPESC. Once efforts are underway, the interim decision process will be utilized for decisions on contracting strategies and use of technical evaluation factors.

m. BCF issues to be addressed:

(1) Deletion of Idoxuridine Ophthalmic Soln - no longer available: Committee concurred. In the future, all discontinued drugs will be automatically removed from the BCF and the committee will be notified at the next scheduled meeting. (CLOSED)

(2) Request from Madigan Army Medical Center (MAMC) to remove blood glucose test strips from BCF: The committee unanimously agreed that test strips should remain on the BCF because of the need to provide a uniform benefit across the Military Health System. COL Moran will prepare and send a response letter to MAMC, explaining the committee's decision. (CLOSED)

(3) Other issues: Mr. Bill Hudson, Humana, asked "When a class is closed, how long is it locked out for?" COL Moran responded that drug classes would only be closed through the issuance of a contract and that most contracts are for five years with annual renewal options. (CLOSED)

n. NMOP Issues to be addressed:

(1) Capt Parrish provided the committee with a brief history and summary of the NMOP program. She explained to the committee that DSCP is utilizing the formulary, prepared by the PEC, as a preferred agent list. If a prescription comes in for something that is not on the list, the mail order contractor, Merck-Medco (M-M), will call the physician and ask if the item can be switched to something that is on the list. If the prescriber does not want to change, then M-M will fill the prescription as written. (CLOSED)

(2) Combination products where both ingredients are currently on the preferred drug list: Since the patient would be required to pay two co-pays and the government two dispensing fees, the committee decided that the majority of such combination products should be added to the NMOP formulary. However, if the cost/benefit ratio comes into question (i.e., the price of the combination product is more than the cost of the two individual ingredients and the two dispensing fees), then the issue will be brought before the committee. (CLOSED)

(3) Dispense as written: The contractor fills between 2,000 and 3,000 such prescriptions per month. The Statement of Work (SOW) states that mandatory generic substitution will be utilized, unless the doctor justifies that a brand name product is necessary. Capt Parrish reviews all of these claims and there are many justifications that are questionable. She suggested that one way to handle such prescriptions is for M-M to FAX the prescriber a standardized form to justify the use of a brand name. Prescriber would be required to return the completed form prior to filling the prescription. If the doctor refuses to fill out the form, the medication will not be dispensed as written. The committee approved this recommendation with a few changes to include the date the physician reported the adverse reaction to the FDA. The following products will be dispensed as written: Birth control pills, carbamazepam (Tegretol®), digoxin (Lanoxin®), phenytoin sodium (Dilantin®), and warfarin sodium (Coumadin®). Currently, thyroids are also dispensed as written. That is to say, Synthroid filled with Synthroid, Levothroid with Levothroid, etc. (CLOSED)

(4) Coverage of antibiotics: Current policy is a maximum of a 21-day supply, if not on the exempt list (approximately 38 anti-infectives – includes antivirals, antifungals, & antibiotics).

The committee agreed that antibiotics should be filled through the NMOP, but only up to a 30-day supply, unless included on the exempt list. If a prescription is received for a greater than 30-day supply and drug is not on the exempt list, but has a definitive FDA approved diagnosis, the prescription will be filled for the greater amount. If the same occurs, but no diagnosis is given, the prescription will be filled for a 30 day supply. The explanation of benefits will direct them to member services to determine how to facilitate the 90 day supply. When a diagnosis is provided, M-M will fill the balance of the prescription and the additional co-pay for the patient will be waived. However, the government will incur the additional dispensing fee expense. CDR Egland will lead a subgroup (CDR Graham, Capt Parrish, and Ms. Doyle) to review the exempt list for potential changes. Capt Parrish will provide him with a printout of questionable greater than 30-day prescriptions. (OPEN)

(5) Coverage of vitamins: The committee decided that no changes need to be made.

(6) Review of product limitations in NMOP: The committee decided the following:

(a) Fertility Drugs – remain as a maximum of 30-day supply. PEC to review and provide recommendation to the committee. (OPEN)

(b) Diabetic Test Strips – change to a maximum of 400 strips per 90 days for insulin dependent diabetics and 100 strips per 90 days for non-insulin dependent diabetics. Same limitations for BCF. (CLOSED)

(c) Insulin syringes – remain at a maximum of 300 per 90 days. Same limitation for BCF. (CLOSED)

(d) Anti-emetics – remain at 15 tablets/30 days to max of 45 tablets/90 days. (CLOSED)

(e) Impotence – Viagra® to remain at maximum of 6 tablets per 30 days. Caverject® and Muse® changed to maximum of 6 per 30 days. (CLOSED)

(f) Migraine therapy – Imitrex® to remain as a maximum of 48 tablets of 25mg, 24 tablets of 50mg, and 8 injections per 30 days. New agents, such as the nasal product will default to the M-M clinical max. The committee recommends that the DoD/VA Practice Guideline Group consider addressing the need for guidelines for treating this condition. A letter will be sent to the group. (OPEN)

(g) High Dollar Pharmaceuticals – to remain unchanged; list includes a 30-day supply for myeloid stimulants, Interferon Alpha, Interferon Gamma, Erythroid stimulants, Sandostatin®, anti-hemophilic factors, and factor IX preps; and includes a 90-day supply for interferon beta, growth hormones, and Copaxone®. (CLOSED)

(h) Retin-A® – to remain unchanged; only to patients up to age 35. (CLOSED)

(i) Prenatal Vitamins – to remain unchanged; only to women up to age 45. Same limitations for BCF. (CLOSED)

COL Hobbs suggested that any future quantity limitations and preferred agent status that applies to the NMOP should also be the same for the retail network. The committee agreed, however, such changes will probably have to be approved by TMA-West.

(7) New FDA approved products – "mapping" to preferred agent list: "Mapping" refers to the process where newly marketed pharmaceuticals, that are not included on the NMOP, are matched against a drug or class of drugs that are on the NMOP. This will allow M-M to call prescribers of these newly marketed pharmaceuticals and request a change. Capt Parrish stated that until a newly marketed agent is "mapped", M-M would not be able to fill any prescriptions

for the agent. The committee's decision was that the PEC would perform all "mapping" of these new agents within 180 days of FDA approval. (CLOSED)

(8) Adderall®: This product is a Class II agent and cannot be "mapped" to another Class II agent because of Federal Regulations. The committee approved addition to the NMOP. (CLOSED)

(9) Coverage of agents specifically excluded by CHAMPUS: The following agents will not be provided by NMOP: lancets, OTC products (unless specifically included), drugs for cosmetic use (i.e., Renova®, Propecia®), devices, Clozaril®, smoking deterrents, injectable medications (unless specifically included), and vitamins (unless specifically included). (CLOSED)

(10) Same drugs, different manufacturers with different prices – NJ law prohibits substitution: These include Desogen®/OrthoCept®, TriPhasil®/Trilevlen®, Prinivil®/Zestril®, and Trandate®/Normodyne®. Capt Parrish requested, and received, the committee's approval to seek alternatives through MM to possibly move the filling of those prescriptions to another state where those items are interchangeable. (CLOSED)

(11) Birth control pills – 28-day packages are cheaper than 21-day packages: Capt Parrish will work with the DAPA section at DSCP to see if 21-day package price could be changed to matched the 28-day package price. (OPEN)

(12) Time limits for refills – SOW currently states that 75% must be used before refilling: Until recently, M-M had been filling all refill requests, regardless of time limit. M-M has been informed that they will follow 75% rule. Now, M-M returns refill requests to patients unfilled, if 75% rule is not met. The committee stated that the needs of the patients have to be considered and that undue hardship should not be placed on them. Mr. Lowe responded that the VA does not return early refill requests, that these are held until the established time limits are met, then the requests are filled and mailed to the patient. COL Strampel asked if this could also be done by M-M. Capt Parrish stated that this would require a modification in the SOW and could possibly cost the government more. Issue is tabled until next meeting by which time Capt Parrish will check to see if and how much a change in the SOW will cost. (OPEN)

o. Viagra® policy: Issues of concern are safety and cost. Since Health Affairs has already written a "draft" policy and it appears that it will be imminently approved, the committee will defer on this issue. (OPEN)

5. ADJOURNMENT: The meeting was held from 1400-1700 on 13 July 1998 and from 0800-1515 on 14 July 1998. The next meeting will be held on 13 November 1998. The office of record for official minutes is the Pharmacoeconomic Center, Fort Sam Houston, TX 78234.

ERROL L. MORAN
COL, MS
Co-chairman

WILLIAM D. STRAMPEL
COL, MC
Co-chairman