



U.S. PUBLIC HEALTH SERVICE
Pharmacist Professional Advisory Committee
Department of Health and Human Services

Minutes of Meeting
06 December 2012
FDA White Oak Conference Room 1419
1400-1530

Members Present

CDR Michael Crockett (Chair), BOP-Pollock, LA
LCDR Marisol Martinez (Chair-Elect), DoD-FT Sam Houston, TX
CAPT Aaron Sigler, FDA-Rockville, MD
CDR Kavita Dada, FDA-Silver Spring, MD
CDR Janelle Derbis, FDA-Chicago, IL
CDR Jinhee Lee, SAMHSA-Rockville, MD
CDR Aaron Middlekauff, DHS-Washington DC
CDR Timothy Murray, IHS-Claremore, OK
CDR Diem-Kieu Ngo (Alt.), FDA-Silver Spring, MD
CDR Juliette Touré, FDA-Silver Spring, MD
CDR MaryJo Zunic, IHS-Albuquerque, NM
LCDR Troy Bernardo, BOP-Butner, NC

LCDR Jeffrey Eertmoed (Alt.), DHS-Tacoma, WA
LCDR Christina Eldridge (Alt.), IHS-Anchorage, AK
LCDR Tiffanie Dunlevy, BOP-FCI Marianna, FL
LCDR Khang Ngo, IHS-Taholah, WA
LCDR Selena Ready, FDA-Silver Spring, MD
LCDR Jodi Tricinella, IHS-Claremore, OK
CDR Timothy Bowman (Assoc.), DHS-Houston, TX
CDR Lori Hall (Assoc.), CDC-Atlanta, GA
LCDR Kenda Jefferson (Assoc.), DHS-Washington DC
LCDR Liatte Krueger (Assoc.), FDA-Parsippany, NJ
LCDR Andrei Nabakowski (Assoc.), OS-Rockville, MD
CDR Peter Diak (Ex-Officio), FDA-Silver Spring, MD
LCDR Rodney Waite, BOP-Milan, MI

*indicates PharmPAC alternate

Excused members: RADM Scott Giberson (CPO), DCCPR-Rockville, MD; CDR Jefferson Fredy, IHS-Crownpoint, NM; CDR Damion Killback (Alt.), ST; LCDR Brittany Keener, IHS-Anchorage, AK*; LCDR Kara King, IHS-Anchorage, AK; CAPT Greg Dill (Assoc.), CMS-Chicago, IL; CDR Fortin Georges (Assoc.), NIH-Bethesda, MD; CDR Carmen Kelly (Assoc.), AHRQ-Rockville, MD

Call to Order: CDR Michael Crockett (mcrockett@bop.gov)

Meeting began at 1400 EST.

CPO Report & Open Forum → RADM Scott Giberson

- Not available for this meeting: **Please see the December PharmPAC CPO Report.**

Readiness Section → CDR Janelle Derbis (Janelle.derbis@fda.hhs.gov) / CDR Juliette Touré (Juliette.toure@fda.hhs.gov) / LCDR Troy Bernardo (Khang.Ngo.USPHS@hotmail.com)

- Deployment: ~75 pharmacy officers out of ~240 deployed for Sandy
- CAPT Beck and LCDR Wyatt held a Q&A session on the line. Below is a summary:

LCDR Wyatt presented the following:

Thanks for understanding the DCCPR's delays due to multiple deployments. As of 1 October 2012 Pharmacy Category has 87% at Basic Ready. Will send out reminders to officers about what is missing for projected status either this weekend (8 and 9 December 2012) or next week (12/10/12-12/15/12). The Basic Ready System is not real-time except for self-reported sections. The remainder is done manually, about weekly, except when approaching deadlines, when the frequency is increased, up to daily the week of the deadline. Officers must get all required items into MAB/system BEFORE the deadline date. Readiness not closed out until the Medical Affairs Branch (MAB) notifies readiness that they entered all information sent in prior to deadline. Please fax information just once for now as there is a delay currently. It takes 3-4 weeks **after** the deadline for MAB to put in all information. Please use the Readiness Assistance Form (http://ccrf.hhs.gov/ccrf/readiness_assistance_form.htm) if documentation issues.

Q: If an officer wants to switch from one Tier 3 roster to another, e.g., roster B to C, how does one accomplish that?

A: 1) Use Readiness Assistance Form to notify that you want to switch and why. Can also e-mail HHS-OFRD.

Q: Is Basic Ready the only readiness option, or are there levels of advanced readiness (available to those not on a rapid deployment team)?

A: Basic Ready is the only readiness level. An officer is considered Basic Ready or Not Basic Ready.

Q: When was the last check on Readiness?

A: The last official readiness check was 30 September 2012. The last unofficial readiness check to assess Projected Status (to see what items are due/overdue for whom) was done the morning of 06 December 2012.

Q: How long does it take for information to get updated in Direct Access? eOPF? Which one is updated first?

A: Varies significantly, but can be up to a couple of days. Self-entered data is immediate. Training courses may take 1-2 days. Immunizations vary based on when MAB enters the information, but usually only takes a few hours to transfer to Direct Access. President's Challenge is periodic, usually once a month and requires an annual certificate of completion.

Q: Can you describe what one should submit for a medical waiver request (e.g., for pregnancy & delivery)? What is the standard timeframe of review, i.e., results are seen on Direct Access?

A: All medical waivers are done by the Medical Waivers branch, not by DCCPR (Readiness). Whenever Readiness is assessing if an officer meets Basic Readiness, they just see that a medical waiver is added, but do not make any determination on the affect that waiver.

- Q: When is President's Challenge phasing out?

A: No plan/policy/official stating that President's Challenge is being phased out.

- Q: I get an error message when trying to enter my physical activities in the President's Challenge website:

When I put in my President's Challenge username and password, nothing happens and I am unable to proceed. Do you know who I could reach out to get technical assistance?

A: Contact the webmaster for that site (1-800-258-8146 (toll free) or e-mail preschal@indiana.edu

CAPT Beck presented the following:

- Q: If you are not able to complete your 80 clinical hours – should one still sign up to deploy as a pharmacist or another deployment role?

A: Some have deployed in a role but were not comfortable in that role, which was not very useful. The 80 clinical hours is a policy requirement for readiness. If in a clinical deployment role, then you must have these 80 hours for that role. If you do not have the 80 hours, then you can have that clinical role as a secondary item. Every officer has the responsibility to NOT choose a role that they do not have the experience/skills for. For example, a pharmacist should not select a hospital pharmacy role if not comfortable in that role. Need to have personal objectivity. If we see non-pharmacist as primary role, then readiness is keyed to assess this.

- Readiness and Promotion: readiness does not measure capability but compliance with policy. Example: if an exemption, then meet requirement because have exemption. Promotion board will automatically “Not Recommend” for promotion if not meet Basic Ready at 12/31 of that year. A second check is done 4/30 of that year and can keep promotion orders from being made. Basic Ready is either Yes or No, a waiver does **not** mean “Yes, with exceptions”.
- Hurricane Sandy operation is winding down. Marianas Island will start next week
- Q: Is initial group ready for Marianas Mission?
A: Yes, they are getting ready to go next week, some will not be able to stay entire time, for example, the pharmacy director role will rotate in ~45-60 days. Some roles not entirely selected to give RADM Kendig time to assess the needs of the situation. More to come on this as determined by mission needs.
- Q: LCDR Jefferson – how long does it take for deployment time credit to show up on record?
A: Corps deployment is defined in policy. If emergency response is part of billet, then “deploying” is not necessarily a corps deployment. An official Corps Deployment must be activated by ASH and is what is necessary for credit, (FMRB, CRSA, etc.). Sometimes, Corps Officers are activated by agencies to assist in roles not normally their day-to-day functions and Corps HQ may get this defined as an Official Deployment. Corps Deployment Credit is not put in eOPF or Promotion Board Packets unless you put it in → if you want to highlight to Promotion Board, then you must highlight in CV under a section that highlights TDYs, deployments, special assignments.
- CDR Touré: use Promotion Checklist and its hyperlinks as it has all the information needed .
 - Promotion Page: <http://dcp.psc.gov/ccmis/promotions/promotions.aspx>
 - Promotion Checklist: http://dcp.psc.gov/CCMIS/promotions/2013_Promotion_Year_Checklist.aspx

- CDR Crockett encourages all officers to get needed items in on time and realize there is a backlog that will not be held against you if put in **BEFORE** the deadline (12/31/2012).
 - CDR Middlekauff: Q: any updates on Swear In Ceremony in January 2013
 - A: Primary assignments have been made. Selections should be announced by CDR Waterman late this week (Week Ending 12/8/2012 or early Week Ending 12/15/2012).
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Communication Section → CDR MaryJo Zunic (MaryJo.Zunic@ihs.gov) / LCDR Khang Ngo (Khang.Ngo.USPHS@hotmail.com) / LCDR Jodi Sparkman (jodi.sparkman@ihs.gov)

- PharmPAC Perspectives Newsletter: thank you to volunteers. Window to volunteer is now closed. E-mail will come out asking for articles and to move accepted volunteers on project. There will be further opportunities to volunteer in future.
 - Publication Webinar: Any ideas you would like to see covered? A request will also be made via Survey Monkey and Listserv.
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Career Development Section → CAPT Aaron Sigler (Aaron.Sigler@fda.hhs.gov) / CDR Jefferson Fredy (jefferson.fredy@ihs.gov) / LCDR Tiffanie Dunlevy (tlmyers@bop.gov)

- LCDR Myers: 2013 Promotion Checklist. On CCMIS Website.
 1. CV Cover Letter and Actual CV need to be submitted prior to deadline (at least a week ahead of 12/31/2012).
 2. OS needs to be faxed in.
 3. ROS should probably already have been mailed to Agency Liaison.
 4. Update licenses and certifications by 12/31/12.
 5. Readiness will be checked 12/31/12 and re-checked 3/30/2012 for promotion.
 - LCDR Myers: 54 senior officers volunteered to review and 75 officers requested to have CV reviews. Any questions or would like a review still email LCDR Myers at (tlmyers@bop.gov)
 - CCPMN: still working on database to try to automate the process. If want to mentor or be mentored, can still contact CDR Ruby Wu @ Chi-Ann.Wu@fda.hhs.gov .
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Administration Section → CDR Kavita Dada (kavita.dada@fda.hhs.gov) / CDR Jinhee Lee (Jinhee.Lee@samhsa.hhs.gov) / CDR Timothy Murray (timothy.murray@ihs.gov) /

- CPO Liaison pending
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Recruitment Section → CDR Aaron Middlekauff (Aaron.p.middlekauff@uscg.mil) / LCDR Brittany Keener (blkeener@anthc.org) / LCDR Kara King (kaking@anthc.org)

- ASHP: very successful with >300 attendees who stopped by our booth.

- UPOC: bi-annual reporting due NLT 15 December 2012. Recruitment Section has a current copy of UPOCs and can provide by request.
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Chair Report → CDR Michael Crockett (mcrockett@bop.gov)

- USPHS Symposium: Junior officers (O-3) or GS-10 or below can apply for scholarship. CDR Watts is looking for officers interested in producing lyrics for pharmacy march for category day. Can contact at JWATTS@cdc.gov
 - Symposium: can check out pictures on site. Please see for “inspiration” to attend. (<http://symposium.phscof.org/>)
 - JOAG:
 1. LCDR Krueger is liaison.
 2. JOAG has O-3 and O-4 officer members from all of the 11 categories.
 3. JOAG General Meetings are held the 2nd Friday of Every Other Month at 1300 EST, upcoming dates are:
 - December 14th, 2012
 - February 8th, 2013
 - April 12th, 2013
 4. Can reach out to any JOAG Committee Chairs for more information.
 5. No formal process to become a general member, just attend meetings and volunteer in projects.
 6. Please join JOAG Listserv (<https://list.nih.gov/cgi-bin/wa.exe?SUBED1=JOAG&A=1>).
 7. Can contact LIATTE.KRUEGER@FDA.HHS.GOV.
 - Ambulatory Special Pay: the Compensation Policy Advisory Board had a meeting 28 November 2012. The Board discussed removing all specific specialty information to allow for payments to those with the Ambulatory Care Specialty, as well as any new specialties developed later. The Board intends to vote on this change at the next meeting in January 2013 and then forward to the Secretary for signature.
 - Commissioned Officer Training Academy is re-starting the Mid-Level course. Initial cadre to start Feb 2013 with 3 officers from each category to work out the kinks before opening up to Senior O-3 and Junior O-4 officers.
 - Promotion: get all items in by 12/31/2012.
 - OBC: Next class 1/3-1/18, PharmPAC will be represented.
 - Recognize RADM Giberson. See Pharmacy Today Magazine (<http://www.pharmacist.com/lead-example-giberson-provides-patient-care-inspires-others>).
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Chair-Elect Report → LCDR Marisol Martinez (Marisol.Martinez@AMEDD.ARMY.mil)

- Marianas Mission: May be a role for Pharmacy Director in February 2013 and 3 more pharmacists.
 1. Link: http://ccrf.hhs.gov/ccrf/Missions/2012_CNMI.htm
 2. E-Mail Questions: OFRD-RESPONSE@hhs.gov
- PharmPAC Perspectives Newsletter: key to success is participation and willingness to submit an article. Stories of accomplishments, deployments, etc.

Old/New Business → CDR Michael Crockett (mcrockett@bop.gov)

- Murray: ASHP Meeting, RADM Giberson gave a great lecture at the Federal Pharmacy Forum.
- Q: Deadline for Jr COSTEP program is 12/31/2012?
A: LCDR Ngo confirms that 12/31/2012 is the deadline.
- Action items for all PHS pharmacists:
 1. Read and Perform Action Items listed in December CPO Report.

The meeting was adjourned @ 1458.

Next Meeting Date: 03 January 2013, from 1400 to 1530 EST, White Oak Conference Room Bldg 22, Room 1419; Agenda and call-in information will be distributed prior to the meeting.

Useful Links and Contact Info:

- ◆ Emails: PharmPAC@list.nih.gov
PHS-Pharmacists@list.nih.gov
PHS-RX-JOBS@list.nih.gov
PHS-Rx-Students@list.nih.gov
- ◆ Listservs: PHS Pharmacists <https://list.nih.gov/archives/phs-pharmacists.html>
PHS Rx Students <https://list.nih.gov/archives/phs-rx-students.html>
OFRD <https://list.nih.gov/cgi-bin/wa.exe?A0=ofrd>
RPh Job Vacancies <https://list.nih.gov/archives/phs-rx-jobs.html>
CCMIS <http://ccmis.usphs.gov/ccmis>
CC Vacancies <https://list.nih.gov/archives/ccvacancies-1.html>
PHS Immunizing Pharmacists <https://list.nih.gov/archives/phs-immunizing-pharm.html>
JOAG <https://list.nih.gov/archives/joag.html>
- ◆ Websites: PharmPAC <http://www.usphs.gov/corpslinks/pharmacy>
CCMIS <http://dcp.psc.gov>
USPHS <http://www.usphs.gov>
OFRD <http://oep.osophs.dhhs.gov/ccrf>
Facebook <http://www.facebook.com/USPHSPharmacists>
JOAG <http://www.usphs.gov/corpslinks/joag/>

--Respectfully Submitted,

Rodney C. Waite _____ / _____ 19 December 2012_____
LCDR Rodney Waite II, Executive Secretary Date

CDR Michael Crockett, Chair / _____
Date

RADM Scott Giberson, CPO / _____
Date

Attachments:

- 1. BOP Liaison Report – Not included this month, not enough new information**
- 2. CDC Liaison Report**
- 3. CMS Liaison Report**
- 4. COA Liaison Report**
- 5. FDA Liaison Report**
- 6. IHS Liaison Report – Not included this month**
- 7. JOAG Liaison Report**
- 8. NIH Liaison Report – Not included this month**
- 9. Recruitment Report**
- 10. CPO Update – Not included this month**

CDC Liaison Report

December, 2012 Updates

Federal Interagency Steering Committee for Adverse Drug Events (ADEs) is launched

On October 24, 2012, a Federal Interagency Steering Committee for Adverse Drug Events (ADEs) co-chaired by the Assistant Secretary for Health (Dr. Howard Koh) and the Deputy Assistant Secretary for Health (Dr. Don Wright), was launched. This Steering Committee is charged with coordinating and aligning ADE efforts across HHS Agencies and other key departments, including the Department of Veterans Affairs. In the initial phases of this effort, the Steering Committee will focus on three high-impact ADE areas (anticoagulants, diabetes agents, and opioids). This work will be modeled after that recently undertaken by the Office of the Assistant Secretary for Health (OASH) and its federal partners to maximize surveillance and prevention efforts around healthcare-associated infections, and will culminate in a Federal Action Plan for Adverse Drug Event Prevention. **RADM Scott Giberson (Chief Pharmacist, USPHS)** is serving as the Office of the Surgeon General representative to the Steering Committee, and **Nadine Shehab, PharmD, MPH (CDC)** is currently on detail to OASH, serving as the acting team lead for this effort.

CDC and Walgreens develop MTM for HIV patients

Set to launch January 1, 2013, CDC and Walgreens have teamed up to develop and test a 3.5-year medication therapy management (MTM) pilot program provided by pharmacists in collaboration with primary care providers at HIV-focused community pharmacies.

“The initiative is in its formative stages and we are still finalizing details related to the overall program,” **Paul Weidle, PharmD, MPH, Pharmacy Officer in CDC’s Division of HIV/AIDS Prevention**, told pharmacist.com. Aiming to improve health outcomes for 1,000 HIV patients, the MTM pilot will include an initial comprehensive medication review and quarterly MTM, as well as monthly services including refill reminders, managing adverse effects, and figuring out insurance benefits, according to Walgreens.

Updates on the HIV testing and linkage to care in community pharmacies and retail clinics project - Epidemiology Branch, Division of HIV/AIDS Prevention, CDC

The goal of this project is to determine how to best implement confidential HIV testing services in community pharmacies and/or retail clinics utilizing pharmacy and retail clinic staff as certified testing providers or through collaborations with other organizations that can provide HIV testing in community pharmacies with referral and linkage to care. A contract was awarded to ASHLIN Management Group, Inc. to implement the project over a two-year project period (Aug 1, 2011 – Jul 31, 2013). The contractor will develop training materials and instructions for providing HIV testing services at community pharmacy and retail clinic locations. A total of 23 pharmacies have been selected. The first seven have started HIV testing, the other 16 are in the set-up phase.

Multistate Outbreak of Fungal Meningitis and Other Infections – Investigation Ongoing

Currently, more than 7 weeks after the three implicated lots of MPA were recalled, CDC continues to receive reports of fungal infection in exposed patients. Previously, the majority of new cases reported to CDC were patients with fungal meningitis following injection. Although cases of fungal meningitis continue to be reported, CDC has recently observed an increase in the number of patients presenting with evidence of epidural abscess, phlegmon, discitis, vertebral osteomyelitis, or arachnoiditis at or near the site of injection. These complications have occurred in patients with and without evidence of fungal meningitis.

CDC Public Health Grand Rounds – Unsafe Injection Practices in the U.S. Healthcare System was held on Tuesday, November 13 and the webcast is now archived for viewing. This program is a designated event for pharmacists to receive 1.0 Contact Hours in pharmacy education. Future Grand Round topics will cover disability and venous thromboembolism (VTE).

Vital Signs: HIV Among Youth in the US. Last month’s Vital Signs report explains that about 50,000 people are infected with HIV each year, and 1 in 4 is 13 to 24 years old. Youth make up 7% of the more than 1 million people in the US living with HIV. About 12,000 youth were infected with HIV in 2010. The greatest number of infections occurred among gay and bisexual youth. Nearly half of all new infections among youth occur in African American males. Read more about what CDC recommends can be done.

CMS Liaison Report

December 2012

CMS Agency Report to PharmPAC

Submitted by CDR Matthew D. Febbo

CMS Pharmacy Officers Deploy to support H. Sandy:



Many CMS Pharmacy Officers have deployed to support H. Sandy, some still deploying currently. CDR Hollie Cook, CMS Regional Pharmacist for the Seattle, Washington Region, is shown above deployed with RDF-3. Great job CDR Cook!

<http://www.examiner.com/article/public-health-service-responds-to-new-jersey-after-hurricane-sandy>

Obama Administration Moves Forward To Implement Health Care Law:

The Obama administration moved forward today to implement provisions in the health care law that would make it illegal for insurance companies to discriminate against people with pre-existing conditions. The provisions of the Affordable Care Act also would make it easier for consumers to compare health plans and employers to promote and encourage employee wellness.

<http://www.cms.gov/apps/media/press/release.asp?Counter=4478&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date>

COA Liaison Report

Commissioned Officer Association (COA) Liaison Report

COA is dedicated to improving and protecting the public health of the United States by addressing unmet health needs and providing support for more than 7,000 members.

Announcements:

Surgeon General Benjamin Honored as Public Health Person of the Week

11/28/2012 - MPH Programs List.com, an online free resource designed to encourage careers in public health, has named PHS Surgeon General, Vice Admiral Regina Benjamin, as its person of the week for the week of November 26th.

MPH Programs List.com launched in February of 2012 as a free resource for students interested in graduate public health, public administration, public policy and health administration programs. The goal is to attract students to these under-served yet highly rewarding fields.

Vice Admiral Benjamin joins a distinguished group of public health leaders recognized by MPH Programs List.com including Thomas Freidan, CDC Director; and Julio Frenk, former Minister of Health for Mexico and now Dean of Faculty at the Harvard School of Public Health.

[Click here for the full story...](#)

What Do PHS Officers Do When Deployed?

11/19/2012 - That's the question answered by an article published on Yahoo! News by Charles Simmins, The article gives a good description of the many critical tasks undertaken by PHS officers when deployed in emergency situations. The Commissioned Corps is the nation's best kept secret and it's always nice to see the Corps get public recognition for the good work our members do in service to the country.

[Click here to read the article.](#)

PHS Commissioned Corps Participate in Veteran's Day Parade in New York City

11/16/2012 - Members of the PHS Commissioned Corps Rapid Deployment Forces deployed to assist in Hurricane Sandy recovery efforts were able to find a few hours of off-duty time to join with the New York COA Branch to march in the New York City Veterans Day Parade last weekend. A total of 54 PHS officers marched in the parade as a unit with Rear Admiral Epi Elizondo, Region VI Health Administrator in the VIP reviewing stands.

New York COA Branch Assists in Hurricane Sandy Relief Efforts

11/07/2012 - The New York COA branch is pitching in to assist in recovery efforts in the aftermath of the Sandy "super storm" that devastated much of New York City, Long Island and the New Jersey coastline last week.

COA members assigned to FDA Jamaica (Long Island) who were not too badly affected by the storm immediately began organizing relief efforts on behalf of NYCOA.

NYCOA also organized support for the two RDF teams deployed to the area. RDF-2 is in Brooklyn and RDF-3 is in Edison, NJ. NYCOA assembled and delivered care packages for each of the teams. The care packages included MWR/comfort items such as water, juice, snacks, blistex, blister care products, exercise equipment and DVDs.

Throughout the recovery from the storm, NYCOA continued preparations to march as a PHS Commissioned Corps unit in the NYC Veterans Day Parade. RADM Epifanio Elizondo, Region VI Health Administrator will join NYCOA members in the Veterans Day Parade.

PHS Commissioned Corps Responds to Hurricane Sandy

10/31/2012 - Selected Units of the PHS Commissioned Corps have been deployed to assist with public health operations along the east coast in the wake of Hurricane Sandy.

93 officers from Rapid Deployment Force (RDF2), Applied Public Health Team (APHT2), Regional Incident Support Teams (RIST1, RIST2, RIST3), National Incident Support Teams (NIST B), are currently deployed in direct support of Hurricane Sandy operations --- this number does not include RECs or other ASPR or OPDIV/STAFFDIV officers engaged directly through their respective agencies.

RDF2 is onsite in New York City awaiting location of FMS. They arrived at 0100 Wednesday morning and immediately engaged at the shelter that was providing temporary billeting by triaging some 100 people coming into the shelter.

Additionally, the following teams are on alert: RDF3, APHT3, NIST C, Mental Health Teams (MHT2, MHT3), Services Access Teams (SAT2, SAT3). These teams represent 250 officers on alert. These teams are also augmented by additional 750 rostered on-call officers.

The volunteer Medical Reserve Corps (MRC) is coordinated through the Office of the Surgeon General and 25 MRC units have also been activated for general/ARC/special medical needs, shelter operations, emergency department outposts, special needs registries and call center support.

Many MRC units have been asked, or have, placed volunteers on standby.

Over 525 volunteers have been deployed by local MRC units in support of this Hurricane Sandy response operations.

FDA Liaison Report

FDA AGENCY REPORT – December 2012

Submitted by LT Sadhna Khatri, PharmD, Office of Communications, Division of Drug Information

Here is a summary of recent product safety, product approvals and announcements to keep you informed about FDA issues. A brief summary of each issue and a web link to detailed information on the FDA website is included.

PRODUCT SAFETY:

[October Safety Labeling Changes](#) (Nov 15)

Safety Labeling Changes includes 58 products with revisions to Prescribing Information.

[Updates on Fungal Meningitis](#) (Nov 2)

Latest information on the New England Compounding Center Meningitis Outbreak

[Pradaxa \(dabigatran etexilate mesylate\): Drug Safety Communication - Safety Review of Post-Market Reports of Serious Bleeding Events](#) (Nov 2)

FDA evaluated new information about the risk of serious bleeding associated with use of the anticoagulants dabigatran (Pradaxa) and warfarin (Coumadin, Jantoven, and generics). Available in [Spanish](#)

[FDA Reports Voluntary Recall of All Ameridose Drug Products](#) (Oct 31)

FDA announced that Ameridose, LLC, based in Westborough, Mass., is voluntarily recalling all of its unexpired products in circulation. Products from Ameridose can be identified by markings that indicate Ameridose by name or by its company logo.

[Over-The-Counter Eye Drops and Nasal Sprays: Drug Safety Communication - Serious Adverse Events From Accidental Ingestion by Children](#) (Oct 25)

FDA is warning healthcare professionals and the public that accidental ingestion by children of over-the-counter eye drops used to relieve redness and nasal decongestant sprays can result in serious and life-threatening adverse events.

For more product safety information, please visit our MedWatch [website](#).

PRODUCT APPROVALS:

[FDA approves first seasonal influenza vaccine manufactured using cell culture technology](#) (Nov 20)

FDA announced the approval of Flucelvax, the first seasonal influenza vaccine licensed in the United States produced using cultured animal cells, instead of fertilized chicken eggs.

[FDA approves pump for heart failure patients awaiting heart transplant](#) (Nov 20)

FDA approved the HeartWare Ventricular Assist System, a left ventricular assist device, to support heart function and blood flow in patients with end-stage heart failure who are awaiting a heart transplant.

[FDA approves first drug-eluting stent to treat peripheral arterial disease](#) (Nov 15)

FDA approved the Zilver PTX Drug-Eluting Peripheral Stent (Zilver PTX Stent), the first drug-eluting stent indicated to re-open a particular artery in the thigh when narrowed or blocked as a result of peripheral artery disease.

[FDA Approves Xeljanz for Rheumatoid Arthritis](#) (Nov 6)

FDA approved Xeljanz (tofacitinib) to treat adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to, or who are intolerant of, methotrexate.

[FDA Expands Use of Xarelto to Treat, Reduce Recurrence of Blood Clots](#) (Nov 2)

FDA expanded the approved use of Xarelto (rivaroxaban) to include treating deep vein thrombosis (DVT) or pulmonary embolism (PE), and to reduce the risk of recurrent DVT and PE following initial treatment.

[FDA Approves Synribo for Chronic Myelogenous Leukemia](#) (Oct 26)

FDA approved Synribo (omacetaxine mepesuccinate) to treat adults with chronic myelogenous leukemia, a blood and bone marrow disease.

For information on drug approvals, please visit [Drugs@FDA](#)

ANNOUNCEMENTS:

[Hernia Surgical Mesh Implants](#) (Nov 16)

FDA's new webpage describes hernias, the different treatment options to repair hernias and recommendations for patients that are considering surgery for their hernias.

[FDA Warns Tennessee Company That Online Product Claims Violate Federal Law](#) (Nov 5)

FDA issued a Warning Letter to The Avalon Effect Inc., for its marketing of a light therapy product that claims to cure or treat symptoms of fungal meningitis, methicillin-resistant Staphylococcus aureus, concussions, Lyme disease, and other diseases.

[Federal Judge Grants Permanent Injunction Against Oregon Herb and Supplement Manufacturer](#) (Oct 25)

A federal judge has granted FDA a permanent injunction against Truman J. Berst, doing business as Alternative Health & Herbs Remedies of Albany, Ore., for selling products represented as herbs and supplements with claims for treating diseases.

[FDA Enters Consent Decree with New York Dietary Supplement Manufacturer, Venus Pharmaceuticals](#) (Oct 25)

Venus Pharmaceuticals International Inc. has agreed to stop production and distribution of

dietary supplements into U.S. commerce and recall and destroy affected product produced prior to January 2012, due to repeated violations of current good manufacturing practice regulations.

RESOURCES:

[The Value of Unique Device Identification \(UDI\) Implementation for Healthcare Systems and Providers](#)

Archived audio and presentation materials are available from the November 5, 2012 webinar.

[FDA Basics Webinar: A Brief Overview of REMS](#)

This presentation will discuss REMS and how they are used to help ensure that the benefits of certain medicines continue to outweigh their risks.

[Consumer Updates](#)

Timely and easy-to-read articles covering all FDA activities and regulated products including:

- [Medication Errors Happen to Pets, Too](#)

[FDA Voice](#)

FDA Voice is the official blog from FDA's senior leadership and staff.

- [Fighting Antibiotic Resistance](#)

[MedSun Medical Product Safety Network](#)

The Medical Product Safety Network (MedSun) improves FDA's understanding of problems with the use of medical devices so that the FDA, healthcare facilities, clinicians, and manufacturers can better address safety concerns. The MedSun Web page is a newsletter-based website which provides monthly updates about timely medical device issues that may impact patient safety.

Interviews

- [Contact Lenses: The Risks You Need to Know](#) - Featuring Bernard P. Lepri, OD, MS, MEd, FDA Office of Device Evaluation, CDRH

- [Decorative Contact Lenses: Truly Frightening](#) - Featuring Michelle Tarver, MD, PhD, FDA Office of Device Evaluation, CDRH

JOAG Liaison Report.
JUNIOR OFFICER ADVISORY GROUP (JOAG)

UNITED STATES PUBLIC HEALTH SERVICE

DATE: December 6, 2012

TO: Pharmacist Professional Advisory Committee

FROM: LCDR Liatte Krueger

SUBJECT: JOAG Liaison Report – INFORMATION

- To all Junior Officers, the Communications and Publications Committee (CPC) is in constant need of article submissions to the JOAG Journal and welcome any ideas that you may have. Please use the “Guidelines for Article Submissions” document, which can be found under the JOAG Journal section of the JOAG website or by clicking on this link: <http://www.usphs.gov/corpslinks/JOAG/journal.aspx>, to assist you with developing and submitting your article. Submit ideas for articles to LCDR William Lanier at william.lanier@fda.hhs.gov and LCDR Gene Gunn at gene.gunn@fda.hhs.gov.
- Journeyman Series Planning Subcommittee is currently soliciting topics for future presentations. If there are topics related to career progression and professional development that you would like to learn more about please submit them (and suggested speaker(s) with contact information, if known) to amay@cdc.gov.
- The November 2012 Career Fair list can be found on the JOAG website at: <http://www.usphs.gov/corpslinks/joag/>. Please contact LT Scott Wiegand at scott.wiegand@ihs.gov or LCDR Caroline Le at Caroline.Le@fda.hhs.gov with any questions. We encourage all junior officers to get out there and represent the Corps!

NEXT JOAG MEETING:

General Member Meeting December 14, 2012; 1300 - 1500 EST.

Call-in information will be provided via JOAG listserv prior to the meetings.