MaineCare Services
An Office of the Department of Health and Human Services
Paul R. LePage, Governor Mary C. Mayhew, Commissioner

Department of Health and Human Services
MaineCare Services
Pharmacy Unit
11 State House Station
Augusta, Maine 04333-0011
Toll Free (866) 796-2463; Fax: (207) 287-8601
TTY Users: Dial 711 (Maine Relay)

TO: Maine Drug Utilization Review Board
DATE: June 17, 2016
RE: Maine DUR Board **Meeting** minutes from June 14, 2016

ATTENDANCE	PRESENT	ABSENT	EXCUSED
Linda Glass, MD	X		
Lisa Wendler, Pharm. D., Clinical Pharmacy Specialist, Maine Medical CTR	X		
Mark Braun, M.D., FACP, Internist/Geriatrician	X		
Mike Antoniello, MD	X		
Kathleen Polonchek, MD			X
Kenneth McCall, PharmD	X		
Steve Diaz, MD	X		
Non –Voting			
Mike Ouellette, R.Ph., Change Healthcare	X		
Jeffrey S. Barkin MD, DFAPA	X		
Jan Yorks-Wright, Pharmacy Supervisor, OMS	X		
Roger Bondeson, Director of Operations, OMS	X		
Christopher Pezzullo, State Health Officer DHHS, DO	X		

Guests of the Board: Jacquelyn Hedlund, MD, Laureen Biczak, DO

CALL TO ORDER: 5:30PM

Dr. Pezzulo called the meeting to order at 5:30 PM.

PUBLIC COMMENTS

Hiren Kachhia from Celgene: Highlighted the attributes of Otezla®.
Jesse Choquette from Teva: Highlighted the attributes of Cinqair®.
Tommy Begers from Adapt: Highlighted the attributes of Narcan Nasal®.
Tammy Curtis from BMS: Highlighted the attributes of Opdivo®.
Craig Young from Abbvie: Highlighted the attributes of Vanclexta®.
Christopher Kant from Allergan: Highlighted the attributes of Viberzi®.
Lance Nicholls from Pfizer: Highlighted the attributes of Xeljanz XR®.

OLD BUSINESS

DUR MINUTES

The February 9, 2016 minutes were approved.

MAINECARE UPDATE

- Dr. Pezzullo welcomed three new board members.
- He also explained that the DUR Board would now be meeting quarterly.
- He explained that he would serve as the acting Chair for this meeting but that a new Chair would be determined in a future meeting.

NEW BUSINESS

FOLLOW UP FROM FEBRUARY DUR MEETING-RETRODUR INTERVENTION: APPROPRIATE TESTOSTERONE USE UPDATE

Dr. Barkin presented the results of the chart review related to testosterone use. There was concern, based on initial data from the RetroDUR investigation, whether testosterone use for MaineCare members was consistent with best practices and guidelines. At the request of the DUR Board, GHS did additional chart review. Charts were chosen from those members who had testosterone prescriptions without a medical billing code seen in the year preceding treatment for recommended laboratory testing, including testosterone levels, CBCs. lipid panels, etc.

GHS excluded those under the age of 21 (8 members) as past chart reviews have shown that the majority of these members were either transgender individuals or males with delayed puberty, for whom testosterone is not being used to treat a deficiency.

GHS chose a random sample of 20 from the original 100 identified and the results demonstrated that:

- 17 supplied chart notes or follow up information and of these:
    - 12 of the 20 had had levels drawn that were appropriately low to warrant treatment
    - 1 member was transgender and no pre-treatment levels were needed
    - 2 were no longer on medication, but had not had testosterone levels on file
    - 2 responded that the member was not their patient and additional queries of the new provider were not responded to
- Additionally:
    - 5 members were also being treated for HIV (commonly presents a need for testosterone supplementation but only after determining that levels are low)
    - About half of members were being treated for depression/psychiatric issues
    - 4 members had a diagnosis of diabetes

Of the 20 providers sampled:

- 10 practice general family medicine
- 4 are endocrinologists
- 2 are HIV specialists

- 1 urologist
- 1 orthopedist
- 1 critical care/pulmonologist
- No trends seen in prescribers (1 member of the sample had 2 separate prescribers for their testosterone but were located at the same practice)

Summary: The majority of cases that were evaluated in detail suggested appropriate treatment.

Board Decision: No action required

PROPOSED RETRODUR INTERVENTION
APPROPIATE UTILIZATION OF ANGIOTENSIN MODULATORS IN PATIENTS WITH DIABETES AND HYPERTENSION

Dr. Hedlund presented the next proposed RetroDUR evaluation. She gave a brief overview of the incidence and serious impact of hypertension and diabetes. Hypertension is a common and serious problem in patients with both type 1 and type 2 diabetes. The incidence of hypertension rises from 5 % at 10 years, to 33% at 20 years and 70% at 40 years. The incidence of hypertension reaches 75-85% in patients with progressive diabetic nephropathy. Hypertension is strongly associated with obesity and hypertensive patients are at increased risk for cardiovascular morbidity and mortality. Early treatment of hypertension is particularly important in the diabetic patient to prevent cardiovascular disease and to slow progression of renal disease and diabetic retinopathy.

The American Diabetes Association guidelines state that pharmacologic therapy for patients with diabetes and hypertension should comprise a regimen that includes either an ACE inhibitor or ARB, but not both, and that multiple drug therapy (including an ACE-I or ARB at maximal doses plus a thiazide diuretic) is generally required to meet blood pressure targets. Additionally, the target blood pressure is systolic blood pressure <140 mm Hg, and the diastolic target is < 90 mm Hg.

In order to evaluate provider compliance with guidelines and possible gaps in care, we will identify members with Diabetes, both type I and type II, who are hypertensive and quantify the use of ACE-I and ARB medications, either alone, or combined with other antihypertensive medications, including thiazide diuretics.

Board Decision: No formal action required, but the Board concurred with moving forward with this RetroDUR evaluation.

HIV-PDL/GUIDELINE REVIEW AND RECOMMENDATIONS

Dr. Biczak presented recommended changes to the Anti-retroviral category.

She explained that the widely respected and accepted NIH HIV Guidelines have had a number of significant changes to the “recommended regimens” for anti-retroviral naïve patients, based largely on newer less toxic drugs becoming available. GHS recommends the following changes to make the MaineCare PDL more consistent with current guideline recommendations:

- Move to non-preferred PDL status: Aptivus®, Crixivan®, Invirase®, Lexiva®, Odefsey®, Rescriptor®, stavudine, Trizivir®, Videx® EC, Viracept®, and Viramune®.
- Move to preferred PDL status: Descovy®, Evotaz®, Isentress, ® lamivudine/zidovudine, and Tivicay®

Board Decision: The Board unanimously approved the recommendation.

NEW DRUG REVIEWS

Adzenys® (amphetamine extended- release**); PDL category**-Stimulants and related agents-long acting.

Adzenys® is indicated for the treatment for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Amphetamine, the active ingredient of Adzenys® XR, is a central nervous system (CNS) stimulant. There was no evidence found to support that Adzenys® XR is safer or more effective than the currently available, more cost effective medications.

Recommendation: Adzenys® be non-preferred

Criteria: 1.) Dosing limits apply, please see dosing consolidation list. 2.) DDI: The concomitant use of Adzenys® XR is contraindicated with monoamine oxidase inhibitors (MAOIs) or within 14 days after discontinuing MAOI treatment.

Bendeka®(bendamustine HCl); **PDL category**- Cancer

Bendeka® is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL; efficacy relative to 1st line therapies other than chlorambucil has not been established) AND for the treatment of patients with indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen. Bendamustine, the active ingredient of Bendeka®, is an alkylating agent. It is active against both quiescent and dividing cells. Nevertheless, the exact mechanism of action is not known.

Recommendation: Bendeka® be non-preferred and require clinical prior authorization to verify diagnosis and prior therapies

Cabometyx® (cobimetinib); **PDL category**- Cancer

Cabometyx® is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy. Cabozantinib, the active ingredient of Cabometyx® is a kinase inhibitor. It has been shown *in vitro* biochemical and/or cellular assays to inhibit the tyrosine kinase activity of MET, VEGFR-1, -2, and -3, AXL, RET, ROS1, TYRO3, MER, KIT, TRKB, FLT-3, and TIE-2. These receptor tyrosine kinases are involved in both normal cellular function and pathologic processes such as oncogenesis, metastasis, tumor angiogenesis, drug resistance, and maintenance of the tumor microenvironment.

Recommendation: Cabometyx® be non-preferred

Criteria: Add DDI for Cabometyx.

Cinqair® (reslizumab); **PDL category** - Antiasthmatic- Antiinflammatory Agents

Cinqair® is indicated as add-on maintenance treatment of patients with severe asthma aged 18 years and older with an eosinophilic phenotype. Cinqair® is not indicated for treatment of other eosinophilic conditions and is not indicated for relief of acute bronchospasm or status asthmaticus. Reslizumab, the active ingredient of Cinqair®, is a humanized interleukin-5 (IL-5) antagonist monoclonal antibody (IgG4k) that is produced by recombinant DNA technology. IL-5 is the main cytokine responsible for growth and differentiation, recruitment, activation, and survival of eosinophils. Reslizumab binds to IL-5, and inhibits the bioactivity of IL-5 by blocking its binding to the alpha chain of the IL-5 receptor complex expressed on the eosinophil surface. Thus, reslizumab reduces the production and survival of eosinophils. Nevertheless, the mechanism of action in asthma has not been definitely established. For IV use only, but not as an IV push or bolus. It should only be administered in a healthcare setting by a healthcare professional prepared to manage anaphylaxis.

Recommendation: Cinqair® be non-preferred

Criteria: 1.) For patients ≥ 18 years of age and under criteria add Cinqair® approval will require inadequate response to guideline based therapy including max inhaled steroids and an eosinophilic phenotype with eosinophilia > 400/mcL.

Darzalex® (daratumumab); **PDL category** -Cancer

Darzalex® is indicated for the treatment of patients with multiple myeloma who have received at least 3 prior lines of therapy, including proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Daratumumab, the active ingredient of Darzalex®, is an immunoglobulin G1 kappa (IgG1k) human monoclonal antibody against CD38 antigen. It is produced in a mammalian cell line (Chinese Hamster Ovary) using recombinant DNA technology. CD38 is a transmembrane glycoprotein (48 kDa) expressed on the surface of hematopoietic cells, including multiple myeloma and other cell types and tissues. Daratumumab binds to CD38 and inhibits the growth of CD38 expressing tumor cells by inducing apoptosis.

Recommendation: Darzalex® be preferred

Descovy® (emtricitabine & tenofovir alafenamide fumarate); **PDL category** -antiretrovirals.

Descovy® is indicated in combination with other antiretroviral agents, for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older. Descovy® is not indicated for use as pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk. Descovy® is a fixed-dose combination tablet containing emtricitabine (a synthetic nucleoside analog reverse transcriptase inhibitor, HIV-1 NRTI) and tenofovir alafenamide (TAF). TAF is prodrug of tenofovir, an acyclic nucleoside phosphonate [nucleotide] analog of adenosine 5'-monophosphate. There is evidence to suggest that Descovy® is less likely to cause renal tubulopathy than similar formulations that contain tenofovir disoproxil fumarate. There is also evidence suggesting that patients on TAF formulations may have less bone loss than those on TDF formulations. Efficacy appears to be similar between the two formulations.

Recommendation: Descovy® be non-preferred

Criteria: Add DDI for Descovy®.

Narcan® Nasal Spray (naloxone hydrochloride); **PDL category** -Narcotics- Antagonists.

Narcan® nasal spray is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system (CNS) depression. Narcan® Nasal Spray (NS) is intended for immediate administration as emergency therapy in settings where opioids may be present. Narcan® NS is not a substitute for emergency medical care. Naloxone hydrochloride (HCl), the active ingredient of Narcan® Nasal Spray, is an opioid antagonist that antagonizes opioid effects by competing for the same receptor sites. It reverses the effects of opioids, including respiratory depression, sedation, and hypotension.

Recommendation: Narcan® Nasal Spray be preferred

Criteria: GHS recommended a quantity limits of 4 units per 28 days (2 boxes per 28 days).

Odefsey® (emtricitabine, rilpivirine HCl & tenofovir alafenamide fumarate); **PDL category** -Antirerovirals

Odefsey® is indicated as a complete regimen for the treatment of HIV-1 infection in patients 12 years of age and older as initial therapy in those with no antiretroviral treatment history with HIV-1 RNA ≤100,000 copies per ml; OR to replace a stable antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA <50 copies/ml) for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Odefsey®.

Recommendation: Odefsey® be non-preferred

Criteria: 1.) add DDI for Odefsey 2.)PA required; 12 years of age and older AND used as initial therapy in those with no antiretroviral treatment history with HIV-1 RNA≤100,00 copies per ml; OR to replace a stable antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA <50 copies/ml) for at least 6 months with no history of treatment failure and no known substitutions associated with resistances to the individual components of Odefsey® AND 3.) must have clinical rationale beyond potentially improved compliance for not being able to meet the medical need with preferred medications or combinations of preferred medications, specifically Edurant and Descovy.

Opdivo® (nivolumab); **PDL category** -Cancer.

Opdivo® is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy; **AND** for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy (patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Opdivo®); **AND** for the treatment of patients with classical Hodgkin lymphoma (cHL) that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and post-transplantation brentuximab vedotin (approved under accelerated approval based on overall response rate and continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials) **AND** for unresectable or metastatic melanoma. Nivolumab, the active ingredient of Opdivo®, is a human monoclonal antibody that blocks the interaction between PD-1 and its ligands PD-L1 and PD-L2. Binding of the PD-1 ligands (PD-L1 and PD-L2) to the PD-1 receptor on T-cells inhibits T-cell proliferation and cytokine production. Nivolumab is an immunoglobulin G4 (IgG4) monoclonal antibody that binds to the PD-1 receptor

and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response.

Recommendation: Opdivo® be non-preferred and require PA to confirm diagnosis and appropriate prior therapy

Otiprio® (ciprofloxacin); **PDL category**- Ear.

Otiprio® is indicated for the treatment of pediatric patients with bilateral otitis media with effusion undergoing tympanostomy tube placement. Ciprofloxacin, the active ingredient of Otiprio®, is a synthetic fluoroquinolone antibacterial. The bactericidal action of ciprofloxacin results from interference with the enzyme DNA gyrase, which is needed for the synthesis of bacterial DNA. There was no evidence at this time to support that Otiprio® is safer or more effective than the currently available, more cost effective medications.

Recommendation: Otiprio® be non-preferred

Portrazza® (necitumumab); **PDL category**- Cancer

Portrazza® is indicated in combination with gemcitabine and cisplatin, for first-line treatment of patients with metastatic squamous non-small cell lung cancer (NSCLC). It is not indicated for treatment of non-squamous non-small cell lung cancer. Necitumumab, the active ingredient of Portrazza®, is an anti-EGFR recombinant human monoclonal antibody of the IgG1 kappa isotype that binds to the ligand binding site of the human epidermal growth factor receptor (EGFR). It binds to the human EGFR and blocks the binding of EGFR to its ligands. Activation of EGFR has been correlated with malignant progression, induction of angiogenesis, and inhibition of apoptosis, thus binding of necitumumab induces EGFR internalization and degradation in vitro.

Recommendation: Portrazza® to be non-preferred with clinical prior authorization to verify diagnosis and appropriate concurrent treatment.

Prestalia® (perindopril arginine/amlodipine); **PDL category** -ACE Inhibitors & Calcium Channel Blockers

Prestalia® is indicated for the treatment of hypertension, to lower blood pressure (BP). It may be used in patients whose BP is not adequately controlled on monotherapy OR it may be used as initial therapy in patients likely to need multiple drugs to achieve BP goals. The use of Prestalia® is not recommended in patients with heart failure. Prestalia® is a combination product containing the ACE-Inhibitor perindopril arginine and the CCB amlodipine besylate. Perindopril arginine is the L-arginine salt of perindopril, which is a pro-drug, hydrolyzed to perindoprilat. Amlodipine is a long-acting dihydropyridine calcium antagonist. There was no evidence at this time to support that Prestalia® is safer or more effective than the currently available, more cost effective medications.

Recommendation: Prestalia® be non-preferred

Criteria: 1.) Prestalia will only be approved for patients ≥ 18 years of age.

Sernivo® Spray (betamethasone dipropionate); **PDL category**- Topical- Corticosteroids

Sernivo® Spray is indicated for the treatment of mild to moderate plaque psoriasis in adult patients. Betamethasone dipropionate, the active ingredient of Sernivo® Spray, is a synthetic, fluorinated corticosteroid. It is known that corticosteroids have a role in immune function, inflammation, and protein regulation; however, the exact mechanism of action of Sernivo® Spray for psoriasis treatment is not known. There was no evidence presented to support that Sernivo® Spray is safer or more effective than the currently available, more cost effective medications.

Recommendation: Sernivo® Spray to be non-preferred; Other recommended brand/generic changes to the category are: 1.) move to non-preferred: betamethasone dipropionate, desoximetasone .25%, fluocinolone acetonide .02%, and Halog® AND 2.) Move to preferred: fluocinonide gel.

Criteria: 1.) Treatment beyond 4 weeks is not recommended.

Spritam® (levetiracetam); **PDL category**- Anticonvulsants

Spritam® is indicated as adjunctive therapy in the treatment of partial onset seizures in patients with epilepsy ≥4 years of age weighing >20kg AND as adjunctive therapy in the treatment of myoclonic seizures in patients ≥12 years of age with juvenile myoclonic epilepsy AND as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients ≥6 years of age with idiopathic generalized epilepsy. Levetiracetam, the active ingredient of Spritam®, is an antiepileptic drug. There is no evidence at this time to support that Spritam® is safer or more effective than the currently available, more cost effective medications.

Recommendation: Spritam® to be non-preferred

Taltz® (ixekizumab); **PDL category**- Antipsoriatics.

Taltz® is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Ixekizumab, the active ingredient of Taltz®, is a humanized immunoglobulin G subclass 4 (IgG4) monoclonal antibody (mAb); it selectively binds with the interleukin 17a (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. There is some evidence at this time to support that Taltz® is more effective than etanercept for several assessed outcomes in two phase 3 studies. Long-term efficacy of Taltz® up to 60 months was assessed and maintained. Currently, there is no evidence comparing Taltz® to drugs other than etanercept.

Recommendation: Taltz® be non-preferred

Criteria: It is recommended to assess for TB infections prior to starting treatment with Taltz.

Venclexta® (venetoclax); **PDL category**- Cancer

Venclexta® is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by an FDA approved test, who have received at least one prior therapy. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Recommendation: Venclexta® be non-preferred for clinical PA to check for diagnosis and appropriate clinical setting.

Criteria: Add DDI for Venclexta®.

Viberzi® (eluxadoline); **PDL category**- GI- Irritable Bowel Syndrome Agents

Viberzi® is indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D). Viberzi® is listed as a Schedule IV drug of the Controlled Substances Act. There was no evidence presented to support that Viberzi® is safer or more effective than the currently available, more cost effective medications.

Recommendation: Viberzi® be non-preferred

Criteria: 1.) It is recommended to discontinue treatment in patients who develop severe constipation for more than 4 days. 2.) Prior failed trials of multiple preferred GI agents must occur first, and 3.) IBS-D dx must be thoroughly documented**.**

Vraylar® (cariprazine); **PDL category**- Antipsychotics, Atypicals

Vraylar® is indicated for the treatment of schizophrenia AND for the acute treatment of manic or mixed episodes associated with bipolar I disorder. The exact mechanism of action is not known; however, it is thought it could be mediated through a combination of partial agonist activity at central dopamine D2 and serotonin 5-HT1a receptors and antagonist activity at serotonin 5-HT2A receptors.

Recommendation: Vraylar® be non-preferred

Criteria: 1.) It is recommended to reduce the Vraylar® dose if it is used concomitantly with a strong CYP3A inhibitor (such as itraconazole, ketoconazole), and 2.) The concomitant use of Vraylar® with a CYP3A4 inducer (such as rifampin, carbamazepine) is not recommended.

Xeljanz® XR (tofacitinib); **PDL category**- Rheumatoid Arthritis

Xeljanz® is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs). A limitation of use is that use in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. Tofacitinib, the active ingredient of Xeljanz® XR, is a Janus kinase (JAK) inhibitor. JAKs are intracellular enzymes that transmit signals from cytokines or growth factor-receptor interactions to influence cellular processes of hematopoiesis and immune cell function. There was no evidence presented to support that Xeljanz® XR is safer or more effective than the currently available, more cost effective medications.

Recommendation: Xeljanz® XR be non-preferred

Criteria: 1.) DDI: The concomitant use of Xeljanz® XR with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine are not recommended, and 2.) The concomitant use of Xeljanz® XR with potent CYP3A4 inducers (e.g. rifampin) is not recommended.

Zembrace® SymTouch (sumatriptan); **PDL category**- Migraine- Serotonin Agonists (5HT)- Injectables

Zembrace® SymTouch is indicated for the acute treatment of migraine with or without aura in adults. Zembrace® SymTouch is not indicated for the prevention of migraine attacks. It should be used only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Zembrace® SymTouch, reconsider the diagnosis before Zembrace® SymTouch is administered to treat any subsequent attacks. Sumatriptan succinate, the active ingredient of Zembrace® SymTouch, is a selective 5-$HT_{1B/1D}$ receptor agonist. There is no evidence at this time to support that Zembrace® SymTouch is safer or more effective than the currently available, more cost effective medications.

Recommendation: Zembrace® SymTouch be non-preferred

Board Decision: The Board unanimously approved all of the above recommendations.

FDA SAFETY ALERTS

Fluconazole Injection, USP, (in 0.9 Percent Sodium Chloride) 200mg per 100ml: Recall - Elevated Impurity
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm489316.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA Drug Safety Communication: FDA adds warnings about heart failure risk to labels of type 2 diabetes medicines containing saxagliptin and alogliptin
http://www.fda.gov/Drugs/DrugSafety/ucm486096.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Opioid Pain Medicines: Drug Safety Communication - New Safety Warnings Added to Prescription Opioid Medications
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm491715.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA Drug Safety Communication: FDA revises warnings regarding use of the diabetes medicine metformin in certain patients with reduced kidney function
http://www.fda.gov/Drugs/DrugSafety/ucm493244.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA Alerts Healthcare Professionals About Clinical Trials with Zydelig (idelalisib) in Combination with other Cancer Medicines
http://www.fda.gov/Drugs/DrugSafety/ucm490618.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA warns consumers about potential risks of using eye drops packaged in bottles with loose safety seals
http://www.fda.gov/Drugs/DrugSafety/ucm490693.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA advises health care professionals that counterfeit BiCNU has been discovered in some foreign countries
http://www.fda.gov/Drugs/DrugSafety/ucm500705.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Information on Clozapine
http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm497790.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Canagliflozin (Invokana, Invokamet): Drug Safety Communication - Clinical Trial Results Find Increased Risk of Leg and Foot Amputations
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm501565.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Aripiprazole (Abilify, Abilify Maintena, Aristada): Drug Safety Communication - FDA Warns About New Impulse-control Problems
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm498823.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Brintellix (vortioxetine): Drug Safety Communication - Brand Name Change to Trintellix, to Avoid Confusion With Antiplatelet Drug Brilinta (ticagrelor)
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm498607.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Fluoroquinolone Antibacterial Drugs: Drug Safety Communication - FDA Advises Restricting Use for Certain Uncomplicated Infections
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm500665.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Nizoral (ketoconazole) Oral Tablets: Drug Safety Communication - Prescribing for Unapproved Uses including Skin and Nail Infections Continues; Linked to Patient Death
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm502073.htm

Board Decision: No action required

ADJOURNMENT: 8:30PM

The next meeting will be held on **September 13, 2016** 5:30p.m. – 8: 00p.m at the Augusta Armory.