

**DUR Committee Agenda
June 9, 2015**

**Office of MaineCare Services, Department of Health and Human Services
Augusta Armory
Augusta, Maine
6:00 to 8:00 pm**

Call to Order: 6:00 pm

Public Comments - Open Session

Old Business:

Approval of Minutes (5 mins)

MaineCare Update (5 mins)

Closed Session:

Financial Discussion (20 mins)

New Business:

A) Naloxone Nasal Injection (15 mins)

Steve Rolfe-MMC

B) New Drug Review (45 mins)

Auryxia

Cholbam

Corlanor

Cosentyx

Cresemba

Evekeo

Evzio

Farydak

Kitabis

Namzaric

Natesto

Natpara

Nuessa

Proair Respiclick

Spiriva Resipmat

Toujeo

C) FDA Safety Alerts (15 mins)

Mucinex Fast-MAX Products: Recall - Incorrect Labeling

Including certain lots of Mucinex Fast-MAX Night Time Cold & Flu; Mucinex Fast-MAX Cold & Sinus;

Mucinex Fast-MAX Severe Congestion & Cough and Mucinex Fast-MAX Cold, Flu & Sore Throat

http://www.fda.gov/Safety/Recalls/ucm444028.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA issues final guidance on the evaluation and labeling of abuse-deterrent opioids

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm440713.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Counterfeit Version of Botox Found in the United States

http://www.fda.gov/Drugs/DrugSafety/ucm443217.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Amyotrophic Lateral Sclerosis (ALS) Statement

http://www.fda.gov/Drugs/DrugSafety/ucm443242.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Chantix (varenicline): Drug Safety Communication - FDA Updates Label to Include Potential Alcohol Interaction

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm437415.htm>

FDA Drug Safety Communication: FDA warns of serious slowing of the heart rate when antiarrhythmic drug amiodarone is used with hepatitis C treatments containing sofosbuvir (Harvoni or Sovaldi) in combination with another Direct Acting Antiviral drug

http://www.fda.gov/Drugs/DrugSafety/ucm439484.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Zyprexa Relprevv (olanzapine pamoate): Drug Safety Communication- FDA Review of Study Sheds Light on Two Deaths Associated with the Injectable Schizophrenia Drug

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm439472.htm>

FDA Drug Safety Communication: FDA warns that SGLT2 inhibitors for diabetes may result in a serious condition of too much acid in the blood

<http://www.fda.gov/Drugs/DrugSafety/ucm446845.htm>

Next meeting: September 8th 2015 6-8pm

Adjournment: 8:00 pm