

New Drug Update 2011

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Changing What's Possible.



Objectives

- Review a selection of medications approved by the Food and Drug Administration (FDA) in 2011
- Discuss FDA market withdrawals and other safety alerts that affect patient care
- Identify resources that can be used to stay up-to-date with actions by the FDA

Changing What's Possible.



New Drug Entity Approvals

- Information is reported by the FDA
- FDA Review Process
 - Regular review
 - Expedited review
 - Orphan disease
 - Fast track designation
 - Accelerated approval program
 - Priority review

Changing What's Possible.



Abbreviations

- | | |
|---------------------------------|--|
| • ACS – acute coronary syndrome | • HR – hazard ratio |
| • ADR – adverse drug reaction | • N – nausea |
| • AF – atrial fibrillation | • NSAIDs – non-steroidal anti-inflammatory drugs |
| • BP – blood pressure | • PR – partial response |
| • BMS – bone marrow suppression | • PAP – patient assistant program |
| • BW – U.S. Boxed Warning | • PE – pulmonary embolism |
| • CV – cardiovascular disease | • SJS – Stevens-Johnson syndrome |
| • CR – complete response | • SVR – systemic virologic response |
| • DVT – deep vein thrombosis | • VTE – venous thromboembolism |
| • D – diarrhea | • V – vomiting |
| • GI – gastrointestinal | |

Changing What's Possible.



2011 Food and Drug Administration

NEW APPROVALS

Changing What's Possible.



Complete list at CenterWatch: <http://www.centerwatch.com/drug-information/fda-approvals/>

CARDIOVASCULAR

Changing What's Possible.



Azilsartan kamedoxomil (Edarbi™)


- Angiotensin receptor blocker (ARB)
- Literature
 - Reductions in BP
 - -14.3 vs -10 vs -11.7 mmHg
- Warnings and ADRs
 - Pregnancy [BW], hypovolemia
 - Similar to other ARBs
- Drug Interactions
 - NSAIDs
- Dose
 - 80 mg PO daily; dose adjust in volume depletion

Protect from Light/Moisture

Pregnancy C/D

Boxed Warning

PAP



Changing What's Possible.

Dabigatran etexilate (Pradaxa®)


- Prevention of stroke
- Literature
 - RE-LY (MC, MN, R, parallel group) compared with warfarin
 - HR 0.65 (0.52 - .081) $P = 0.0001$
- Warnings and ADRs
 - Bleeding; FDA safety alert in December 2011
 - No reversal guidelines
 - GI events
- Drug Interactions
 - P-glycoprotein inducers, dronedarone, ketoconazole, clopidogrel, St. John's wort
 - Medications that bleeding
- Dose
 - 150 mg PO twice daily; renal adjustments
 - Conversions and discontinuations

Protect from Moisture

LASA

Med Guide

PAP



Changing What's Possible.

Ticagrelor (Brilinta™)

- Reduction of thrombotic events ACS
- Literature
 - PLATO: compared with clopidogrel
 - Efficacy: 9.8% vs 11.7%
 - Safety: 11.6% vs 11.2% [major bleeding]
- Warnings and ADRs
 - Bleeding [BW], dyspnea
- Drug Interactions
 - CYP3A4 inhibitors and inducers, digoxin, simvastatin/lovastatin
 - Medications that affect bleeding
- Dose
 - 180 mg PO loading dose; 90 mg PO twice daily
 - Aspirin therapy


REMS

Med Guide

Protect from Moisture

Boxed Warning

PAP



Changing What's Possible.


Rivaroxaban (Xarelto®)

- Indications
 - Reduction of stroke and systemic embolism from AF
 - Prophylaxis of DVT during knee or hip replacement
- Literature
 - RECORD 1, 2, 3; ROCKET; EINSTEIN
 - Total VTE: RRR – 48% to 76%
 - AF: noninferior to warfarin
- Warnings and ADRs
 - Spinal/epidural hematoma [BW]
 - Bleeding
- Drug Interactions
 - CYP3A4 inhibitors and inducers; medications that affect bleeding
- Dose
 - 10 mg or 20 mg PO daily

Boxed Warning

Med Guide

PAP




Changing What's Possible.

Quick Stop Question 1

- After obtaining a medical history for a newly admitted patient, you notice on the H&P that the patient is pregnant.
 - PMH: hypertension, 8 weeks pregnant, constipation
 - Medications: prenatal vitamin, azilsartan, docusate
- What recommendation do you have for the medical team?

Changing What's Possible.




Quick Stop Question 1

X


Changing What's Possible.

http://www.pollyeverywhere.com/multiple_choice_polls/MTC3Mzk1MDI4



Quick Stop Question 2

- New admitted patient is undergoing total hip replacement. The medical team has a concern about the use of warfarin in this patient.
- What new anticoagulant could be used to reduce the risk of DVT?




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Changing What's Possible.

Quick Stop Question 2

X




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Changing What's Possible.

http://www.poll Everywhere.com/multiple_choice_polls/LTE5NDgzODEyMDM

HEMATOLOGY/ONCOLOGY



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Changing What's Possible.

Crizotinib (Xalkori®)


- Advanced or metastatic non-small cell lung cancer that is anaplastic lymphoma kinase +
- Literature
 - 3 CRs and 136 PRs for 50% response rate
 - Response duration ≈ 40-48 weeks
- Warnings and ADRs
 - Pneumonitis, hepatic effects, QT prolongation
 - Vision disorder, N, V, D, edema, constipation, increased ALT, neutropenia
- Drug Interactions
 - CYP3A4 inhibitors/inducers, drugs that prolong the QT interval, drugs that elevate the gastric pH, grapefruit
- Dose
 - 250 mg PO twice daily; dose adjustments for hematologic toxicities

FDA Expedited Review

PREGNANCY D

Specialty Pharmacy

PAP



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Changing What's Possible.

Ipilimumab (Yervoy™)

- Unresectable or metastatic melanoma
- Literature
 - Survival at 1 year – 46% vs 25%
 - Median overall survival ≈ 10 months
- Warnings and ADRs
 - Immune-mediated reactions [BW]
 - Fatigue, diarrhea, pruritus, rash, colitis
- Drug Interactions
 - Potential: digoxin, warfarin
- Dose
 - 3 mg/kg IV (over 90 min) every 3 weeks for 4 doses
 - Must dilute and use an in-line filter
 - Adjust schedule/dose for toxicities

FDA Expedited Review


Protect from Light

REMS

Med Guide

Boxed Warning

PAP



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Changing What's Possible.

Vemurafenib (Zelboraf™)

- Unresectable or metastatic melanoma with BRAF^{V600E} mutation
- Literature
 - Treatment naive: overall response – 48% vs 5%
 - Median survival – 5.3 months vs 1.6 months
 - Prior therapy: overall response – 52%
- Warnings and ADRs
 - Cutaneous squamous cell carcinoma, dermatologic reactions, QT prolongation, liver abnormalities, ophthalmic effects
 - Edema, alopecia, arthralgia, fatigue, N, photosensitivity, rash
- Drug Interactions
 - CYP3A4 and P-glycoprotein inhibitors/inducers, drugs that prolong the QT interval, warfarin
- Dose and Administration
 - 960 mg PO twice daily; dose adjustments for toxicities
 - Swallow with full glass of water; do not crush or chew

FDA Expedited Review


PREGNANCY D

LASA

Specialty Pharmacy

Med Guide

PAP



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Changing What's Possible.

Abiraterone acetate (Zytiga™)

- Metastatic, castration-resistant prostate cancer
- Literature
 - Mean overall survival – 14.8 m vs 10.9 m
 - Trial terminated early
- Warnings and ADRs
 - Pregnancy, hepatotoxicity, CV disease
 - Edema, triglycerides, electrolytes, diarrhea, LFTs, hypertension, hot flush
- Drug Interactions
 - CYP3A4 and P-glycoprotein inhibitors/inducers
- Dose
 - 1000 mg PO daily (prednisone 5 mg PO twice daily)
 - Dose adjustments in hepatic impairment

Changing What's Possible.

Brentuximab vedotin (Adcetris™)

- Refractory Hodgkin lymphoma (HL) and systemic anaplastic large cell lymphoma (sALCL)
- Literature
 - HL: overall response rate – 73%
 - sALCL: overall response rate – 86%
- Warnings and ADRs
 - Progressive multifocal leukoencephalopathy (PML)[BW]
 - Bone marrow suppression, peripheral neuropathy, SJS
- Drug Interactions
 - Bleomycin (contraindicated)
- Dose
 - 1.8 mg/kg IV every 3 weeks [maximum: 180 mg]
 - Administer over 30 minutes; do not push
 - Dose adjustments for toxicities

Changing What's Possible.

Vandetanib (Caprelsa®)

- Metastatic, advanced thyroid cancer
- Literature
 - Progression-free survival – HR = 0.35 [0.24-0.53]
 - Overall response rate – 44% vs 1%
- Warnings and ADRs
 - QT prolongation [BW]
 - N, D, rash, acne, hypertension, pulmonary toxicity
- Drug Interactions
 - CYP3A4 inhibitors/inducers, drugs that prolong the QT interval, St. John's wort
- Dose
 - 300 mg PO daily
 - Dose adjustment in renal impairment and QT prolongation

Changing What's Possible.

Eribulin mesylate (Halaven™)

- Late stage metastatic breast cancer
- Literature
 - Increased survival: 2.5 months
- Warnings and ADRs
 - BMS, peripheral neuropathy, QT prolongation
 - Fatigue, alopecia, N, V, D, constipation, increased ALT
- Drug Interactions
 - Drugs that prolong the QT interval
- Dose
 - 1.4 mg/m²/dose IV, days 1 and 8 [21-day cycle]
 - Dose adjustments in renal and hepatic impairment, toxicities
 - Infuse over 2 to 5 min (diluted or undiluted)

Changing What's Possible.

Deferiprone (Ferroprox®)

- Chelating agent – treatment of transfusional iron overload
- Literature
 - ≥ 20% decline in serum ferritin: 50% [43%-27%]
- Warnings and ADRs
 - Agranulocytosis [BW], hepatotoxicity, QT prolongation
 - N, V, abdominal pain, chromaturia, headache, arthralgia
- Drug Interactions
 - Mineral supplements, antacids with polyvalent cations
- Dose
 - 25 to 33 mg/kg PO three times daily
 - Round to nearest 250 mg; maximum – 99 mg/kg/day
 - Interrupt therapy for ANC < 1500/mm³

Changing What's Possible.

Quick Stop Question 3

- Like many of the medications approved for cancer, vandetanib help address an unmet medical need for advanced thyroid cancer.
- What type of FDA expedited review did vandetanib receive?

Changing What's Possible.

Quick Stop Question 3

Changing What's Possible.
http://www.polleverywhere.com/multiple_choice_polls/LTE0NzUxOTYvNTE

INFECTIOUS DISEASE IMMUNOLOGY

Changing What's Possible.

Fidaxomicin (Difcid™)

- Treatment of *Clostridium difficile*-associated diarrhea
 - Bactericidal; MIC range 0.03 – 0.25 mcg/mL
- Literature
 - Non-inferior to oral vancomycin
 - Clinical response: 88% vs 86%/87%
 - Sustained clinical response: 70%/72% vs 57%
- Warnings and ADRs
 - Not for treatment of systemic infections
 - N, V, abdominal pain, GI hemorrhage, anemia, neutropenia
- Drug Interactions
 - None reported
- Dose
 - 200 mg PO twice daily [10 days]
 - No adjustments needed for renal or hepatic impairment

Changing What's Possible.

Boceprevir (Victrelis™)

- Treatment of chronic hepatitis C
- Literature
 - SPRINT-2: SVR – 66% vs 63% vs 38%
 - RESPOND-2: SVR – 66% vs 59% vs 21%
- Warnings and ADRs
 - Substrates/inducers of CYP3A4, serious skin reactions
 - Fatigue, anemia, N, headache, dysgeusia
- Drug Interactions
 - CYP3A4 substrates/inducers, warfarin, digoxin, colchicine
 - Ritonavir-boosted HIV protease inhibitor regimens
- Dose
 - 800 mg PO three times daily [with food]
 - Peginterferon alfa and ribavirin
 - Response-guided therapy based on HCV-RNA results

Changing What's Possible.

Telaprevir (Incivek™)

- Treatment of genotype 1 chronic hepatitis C
- Literature
 - Overall SVR = 74% vs 46%
 - On-treatment virologic failure = 7% vs 29%
- Warnings and ADRs
 - Substrates/inducers of CYP3A4
 - Pruritis, anemia, N, V, D, hemorrhoids, dysgeusia
- Drug Interactions
 - CYP3A4 substrates/inducers, warfarin, digoxin, colchicine
- Dose
 - 750 mg PO three times daily [with food]
 - Peginterferon alfa and ribavirin
 - Response-guided therapy based on HCV-RNA results

Changing What's Possible.






Rilpivirine (Edurant™)

- Treatment of HIV
- Literature
 - Non-inferior to efavirenz in combination with fixed regimen
 - Undetectable viral load: 84.3% vs 82.3%
- Warnings and ADRs
 - CYP3A4 inducers, drugs that increase gastric pH, depressive disorders, fat redistribution, immune reconstitution syndrome
 - Insomnia, headache, rash, liver enzyme changes
- Drug Interactions
 - CYP3A enzyme inhibitors, drugs that prolong the QT interval, proton pump inhibitors
- Dose
 - 25 mg PO daily [with a meal]

Changing What's Possible.

Belimumab (Benlysta®)


- Systemic lupus erythematosus
 - Autoantibody-positive [ANA and/or anti-ds-DNA]
- Literature
 - SLE Responder Index
 - Trial 2: 34% vs 41% vs 43% Trial 3: 44% vs 51% vs 58%
- Warnings and ADRs
 - Infusion reaction, serious infections, malignancy, psychiatric effects, live immunizations
 - N, D, pyrexia, insomnia, pain in extremity, depression, migraine
- Drug Interactions
 - Live immunizations, others not well documented
- Dose
 - 10 mg/kg IV at 2-week intervals [3 doses]; then 4-week intervals
 - Infuse over 1 hour

ANA – antinuclear antibody; anti-ds-DNA – anti-double-stranded DNA





Roflumilast (Daliresp®)

- Chronic obstructive pulmonary disease
- Literature
 - Reduction in rate of exacerbations (15%, 18%)
 - Only significant in severe COPD with associated chronic bronchitis or exacerbations in the previous year
- Warnings and ADRs
 - Moderate-to-severe liver impairment, CNS, weight loss
 - N, D, weight decrease, headache, back pain, insomnia, dizziness, decreased appetite
- Drug Interactions
 - Strong CYP3A4 inducers/inhibitors, contraceptives
- Dose
 - 500 mcg PO daily



Belatacept (Nujolix®)

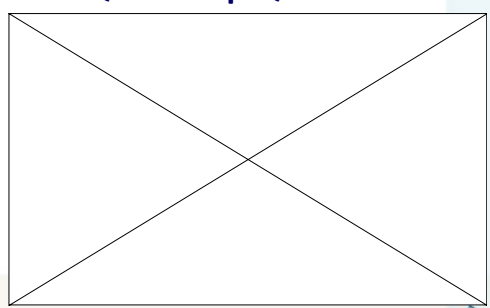
- Organ rejection – kidney transplant
- Literature
 - Efficacy failure: 21.7% vs 16.7%
- Warnings and ADRs
 - Posttransplant lymphoproliferative disorder [BW], progressive multifocal leukoencephalopathy (PML), malignancies [BW], serious infections [BW]
 - Anemia, N, V, D, UTI, edema, constipation, headache, pyrexia, graft dysfunction
- Drug Interactions
 - Medications that may be affected by immunosuppression
- Dose
 - 10 mg/kg IV days 1 and 5; weeks 2 and 4; weeks 8 and 12
 - 5 mg/kg IV week 16; then every 4 weeks
 - Infuse over 30 minutes; low-protein-binding filter

Quick Stop Question 4

- For a number of these medications, there are significant interactions with the CYP enzyme system.
- What herbal medication is contraindicated or should be used with caution in medications that are metabolized by CYP3A4?

Quick Stop Question 4





http://www.polleverywhere.com/multiple_choice_polls/ITESMDg5MDU5Nzk

OTHER DISEASE STATES OR INDICATIONS

Linagliptin (Tradjenta™)




- Type II diabetes
- Literature: change in A_{1c}
 - Monotherapy: -0.4% vs -0.1%
 - Combination
 - Metformin: -0.5% vs 0.15% Glimepiride: -0.4% vs -0.6%
 - Pioglitazone: -1.1% vs -0.6% Sulfonylureas: -0.5% vs 0.1%
 - Metformin + sulfonylureas: -0.7% vs -0.1%
- Warnings and ADRs
 - Nasopharyngitis, hypoglycemia, pancreatitis
- Drug Interactions
 - Strong CYP3A4 and P-glycoprotein inducers, sulfonylureas
 - Ethanol; herbs/nutriceuticals with hypoglycemic properties
- Dose
 - 5 mg PO daily

Changing What's Possible.

Vilazodone (Viibryd™)

- Major depressive disorder
- Literature
 - Superior to placebo in MADRS – 8 weeks
 - Change from baseline: -3.2 [study 1]; -2.5 [study 2]
- Warnings and ADRs
 - Suicidal thinking/behavior [BW], serotonin syndrome, neuroleptic malignant syndrome, abnormal bleeding, hyponatremia
 - N, V, D, insomnia
- Drug Interactions
 - MAOI inhibitors, CYP3A4 inhibitors/inducers, serotonergic drugs, aspirin, NSAIDs
- Dose
 - Titrate up to 40 mg PO daily [with food]
 - Dose adjustments for strong and moderate CYP3A4 inhibitors









Changing What's Possible.

MADRS – Montgomery-Asberg Depression Rating Scale

Ezogabine (Potiga™)






- Adjunctive treatment of partial onset seizures
- Literature
 - Reduction in 28-day seizure frequency
- Warnings and ADRs
 - Neuropsychiatric symptoms, urinary retention, QT prolongation, suicidal ideation
 - Dizziness, somnolence, fatigue,
- Drug Interactions
 - Phenytoin, carbamazepine, digoxin
- Dose
 - Titrate up to 400 mg PO three times daily
 - Dose adjustments in renal failure and geriatric patients

Changing What's Possible.

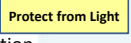

Clobazam (Onfi™)

- Seizures associated with Lennox-Gastaut syndrome
- Literature
 - Reduction in weekly frequency of drop seizures and overall seizure frequency
- Warnings and ADRs
 - Somnolence, sedation, drooling, constipation, aggression, insomnia, dysarthria, fatigue
- Drug Interactions
 - CNS depressants, CYP3A4 substrates
- Dose
 - Titrate up to 20 mg PO twice daily
 - Dose adjustments for hepatic impairment and CYP2C19 poor metabolizers








Changing What's Possible.

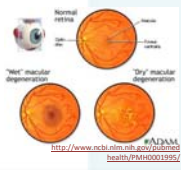
Aflibercept (Eylea™)

- Neovascular (wet) age-related macular degeneration
- Literature
 - Maintained vision: ≈ 95% in all treatment arms
- Warnings and ADRs
 - Endophthalmitis, retinal detachments, increased intraocular pressure
 - Conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters
- Drug Interactions
 - None reported
- Dose
 - 2-mg intravitreal injection
 - Every 4 weeks [3 months]; every 8 weeks [2 months]





Changing What's Possible.




#ADAM
http://www.ncbi.nlm.nih.gov/pubmed/220001397
health/PAH0001397/

Icatibant (Firazyr®)

- Acute attacks of hereditary angioedema
- Literature
 - Median time to 50% reductions: ≈2 h vs 19 h
- Warnings and ADRs
 - Injection site reactions, pyrexia, dizziness, rash, transaminase increase
- Drug Interactions
 - Potential: ACE inhibitors
- Dose
 - 30 mg SC [at 6 hour intervals if needed]
 - No more than 3 injections per 24 h




Changing What's Possible.

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NEW DOSAGE FORMS

Changing What's Possible.



- Azilsartan/chlorthalidone (Edarbyclor™)
- Bupivacaine liposome injectable suspension (Exparel®)
- Bupropion extended release (Forfivo XL)
- Emtricitabine/rilpivirine/tenofovir (Complera™)
- Fentanyl sublingual tablets (Abstral®)
- Fentanyl nasal spray (Lazanda®)
- Gabapentin encarbil (Horizant™)
- Gabapentin (Gralise™)
- Ibuprofen/famotidine (Duexis®)
- Ipratropium/albuterol (Combivent® Respimat®)
- Nevirapine extended release (Viramune® XR™)
- Nitroglycerin (Rectiv™)
- Oxycodone (Oxecta®)
- Zolpidem sublingual tablet (Intermezzo®)


Changing What's Possible.



2011 Food and Drug Administration

MEDICATION SAFETY ALERTS


Changing What's Possible.



- Acetaminophen – limit to 325 mg/dosage unit
- Citalopram – abnormal heart rhythms
- Dabigatran – serious post marketing bleeding events
- Drospirenone – increased risk of blood clots
- Drotrecogin alfa – market withdrawal
- Fluconazole –treatment associated with birth defects
- Ipilimumab – severe immune-mediated reactions
- Lansoprazole ODT – clogged oral syringes/feeding tubes
- Linezolid – serious CNS reactions with psychiatric medications
- Lopinavir/ritonavir –premature babies
- Rosiglitazone – REMS
- Simvastatin – label and dose changes
- SSRIs – use during pregnancy
- Varenicline – risk of cardiovascular events

Changing What's Possible.


<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm238512.htm>




2012 Pipeline

- Approvals
 - Axitinib (Inlyta®)
 - Glucarpidase (Voraxne®)
 - Ingenol mebutate (Picato®)
 - Ivacaftor (Kalydeco™)
 - Mifepristone (Korlym™)
 - Tafluprost (Zioptan™)
 - Vismodegib (Erivedge™)

Changing What's Possible.



2012 Pipeline

- AHJP: Projecting future drug expenditures – 2012
 - Acridinium bromide – COPD
 - Apixaban – anticoagulant
 - Carfilzomib – multiple myeloma
 - Droxidopa – symptomatic neurogenic orthostatic hypotension
 - Linaclotide – irritable bowel syndrome
 - Lucinactant – respiratory distress syndrome in prematurity
 - Pedinesatide – anemia in chronic kidney disease
 - Pixantrone – non-Hodgkin's lymphoma
 - Ridaforolimus - sarcoma
 - Taliglucerase alfa – Gaucher disease
 - Vincristine liposomes – acute lymphocytic leukemia

Changing What's Possible.

Am J Health-Syst Pharm. 2012;69:405-21.

<http://www.ahjp.org/content/69/5/405.full.pdf.html?sid=ef0499e2-7195-461b-92cb-82f3031cddcc>



Staying Current

- FDA CDER:
 - <http://www.fda.gov/Drugs/default.htm>
 - Listserv or RSS Feeds
 - Drugs@FDA
- Medscape
 - www.medscape.com
- CenterWatch
 - <http://www.centerwatch.com/>

Changing What's Possible.



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Changing What's Possible.



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