1.5 ANCC Contact Hours

Catching Up on New Medications

New FDA Approvals

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Despite all efforts of the Federal Drug Administration to release timely and accurate information about new drug approvals, marketing and media announcements about new drugs may be incomplete, misinterpreted, or misunderstood. Informed and knowledgeable nurses are able to educate patients about new medications: they can clarify misunderstandings or misconceptions and significantly reduce the potential for harm. In this article, selected examples of new brand name drugs and first-time generics approved this year are discussed.

Nurses are educators. If one were to ask "which nursing intervention has the most impact on a patient's health and safety?" educating patients about their medications would undoubtedly be near the top of the list in every practice arena. Often, patient education involves explaining all aspects of a new medication and making sure the patient truly understands the important aspects of their new medication. At other times it means correcting misinformation or mistaken ideas about medications the patient has been taking for some time. Information from neighbors, friends, or public media may be inaccurate, incomplete, or misunderstood and can contribute to dangerous medication errors and serious or even fatal results. Knowledgeable nurses, teaching patients about their medications and correcting misinformation, can thus be one of the major factors in preventing medication misadventures and reducing the potential for harm.

In the discussion below, selected examples from the Federal Drug Administration (FDA) approval lists for the first part of this year are reviewed. These examples include new drugs in existing drug classifications and some drugs that are the first in a new drug classification. In addition, generic drugs are discussed and examples of first-time generic approvals are identified.

New Drug Approvals

New drugs identified below include a new combination antibiotic for complicated intra-abdominal or urinary tract infections, a new antifungal for rare fungal infections, and several agents that slow the disease progression in certain types of cancer. Also discussed are two new treatments that reduce hospitalization from worsening heart failure and a new cholesterol-lowering drug. In addition, there is a new anticoagulant, antidiarrheal medications for those with irritable bowel syndrome, and a new option for treating plaque psoriasis (FDA, 2015a) (see Table 1).

One of the areas of focused attention in drug development is the need for new antibiotics and new antifungals. This is increasingly important in light of growing antimicrobial drug resistance. In fact, the FDA has a specific program—Generating Antibiotic Incentives Now—that designates certain products that focus on life-threatening infections as a Qualified Infectious Disease Product (QIDP). Additional support and incentives are available through this program for drug development (FDA, 2015b). Avycaz (cefriazidime/avibactam) is the fifth antibacterial approved under the QIDP designation. This is a fixed combination of an older cephalosporin (2 g) with a new beta-lactamase inhibitor (0.5 g) that is specific for treating complicated intra-abdominal infections in combination with metronidazole and complicated urinary tract infections when there are no alternative treatments. Administration is one dose (1 g/0.5 g) every 8 hours to infuse over 2 hours for 5–14 days. Dose and frequency must be adjusted for changing renal function (daily creatinine clearance). Major side effects include nausea, vomiting, constipation, and anxiety. Hypersensitivity (allergic reaction) may occur patients with known history of penicillin allergy should be monitored closely.

Another drug that received designation as a QIDP is Cresemba (isavuconazonium sulfate). This is a new azole antifungal agent used to treat adults with invasive aspergillosis and invasive mucormycosis: rare but life-threatening infections that occur primarily in individuals with weak immune systems. Cresemba comes both in oral form and vials for intravenous administration. Dosing regimen is either one vial or two capsules every 8 hours for 6 days and then maintenance dose of one vial or two capsules daily. All other medications must be reviewed because there are multiple drug/drug interactions with this medication. Patient monitoring with both

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Table 1. Examples of New Drug Approvals (January to July 2015)

Brand Name	Generic Name	Indication/Route
Avycaz	Avibactam/ceftazidime	Intra-abdominal infection, urinary tract infection (IV)
Corlanor	Ivabradine	Chronic heart failure (oral)
Cosentyx	Secukinumab	Plaque psoriasis (sub-Q)
Cresemba	Isavuconazonium	*Aspergillus* and *Mucorales* fungi infections (IV oral)
Entresto	Sacubitril/valsartan	Heart failure (oral)
Farydak	Panobinostat	Multiple myeloma (oral)
Ibrance	Palbociclib	Metastatic breast cancer (oral)
Lenvima	Lenvatinib	Thyroid cancer (oral)
Praluent	Alirocumab	Heterozygous familial hypercholesterolemia (sub-Q)
Savaysa	Edoxaban	Anticoagulant (oral)
Viberzi	eluxadoline	Antidiarrheal for diarrhea-predominant IBS (oral)
Xifaxan	Rifaximin	Antidiarrheal for diarrhea-predominant IBS (oral)

Note. IBS = irritable bowel syndrome; IV = intravenous; sub-Q = subcutaneous.

oral and intravenous administration is vital: serious liver, hypersensitivity, and skin reactions have been reported.

In the field of oncology, several new drugs were approved. These are not cures, but rather, they each appear to slow the progression of a specific type of cancer when included as part of a focused drug regimen. Ibrance (palbociclib) is an oral agent for use in conjunction with letrozole for treating advanced metastatic breast cancer in postmenopausal women. Ibrance was granted accelerated approval when clinical evidence showed that adding Ibrance almost doubled the life-expectancy of those treated with letrozole alone. Lenvima (lenvatinib) was approved for treating progressive thyroid cancer in patients whose disease has not responded to radioactive iodine therapy. Results of clinical trials indicated a significant reduction in progression of thyroid cancer. Farydak (panobinostat) is an oral drug indicated for multiple myeloma in patients who have received at least two previous regimens including an immunomodulatory agent and bortezomib. Clinical trials showed that including Farydak in a regimen of bortezomib and dexamethasone improved progression-free survival rates greater than without Farydak.

For those patients with heart failure, there are two new oral drugs (Corlanor and Entresto) that received expedited FDA review. The expedited review process is applied to drugs that address a life-threatening disease (or condition) and provide a significant improvement over currently available therapy. Corlanor (ivabradine) is a new oral agent indicated for reducing the risk of hospitalization for patients who have stable, but symptomatic chronic heart failure who have a resting heart rate greater than 70 and are on maximum dosage beta-blockers or for whom beta-blockers are contraindicated. This drug primarily acts on the sinoatrial node to block the hyperpolarization channel responsible for the cardiac pacemaker. It is taken at 5 mg with meals for 2 weeks, then dose is adjusted to the desired resting heart rate of 50–60. Once the heart rate is stable, Corlanor can be used as needed (prn) with dose not to exceed 7.5 mg twice daily. Most common side effects are bradycardia, hypertension, or atrial fibrillation. Pregnancy precautions should be observed. Entresto (sacubitril/valsartan) is the first drug in a new classification of drugs: ARNI medicines. This is a combination of older valsartan (an angiotensin II receptor blocker [ARB] and sacubitril (a new neprilysin inhibitor [NI]). This combination acts to reduce the strain on the failing heart by dilating blood vessels and reducing blood pressure. Entresto may be used in place of traditional angiotensin-converting enzyme inhibitors (ACEs) or ARBs. This oral medication is taken twice daily with dosage adjusted every 2–4 weeks to the target maintenance dose. Most common side effects are angioedema and hypotension. It should not to be used in the second or third trimester of pregnancy or when breastfeeding.

Another drug in a completely new class of drugs is Praluent (alirocumab), a cholesterol-lowering treatment for patients with heterozygous familial hypercholesterolemia (HeFH) when statins, even at maximum doses, are ineffective. HeFH is an inherited condition that causes high levels of low-density lipoprotein (LDL) cholesterol and significantly increases the risk for heart attack. Praluent acts to markedly increase the number of LDL receptors in the liver so that more LDL cholesterol is removed from the blood, resulting in lower LDL cholesterol levels. It comes in in prefilled syringes and injector pens for biweekly subcutaneous injection by patients (or caregivers). Recommended dose is 75 mg/mL. If, after 4–8 weeks, results are inadequate, the dosage can be titrated higher. Most common side effects are nasopharyngitis and flu although hypersensitivity (allergic) reactions (some serious) have been reported.

Savaysa (edoxaban) is a new oral anticoagulant drug approved for reducing the risk of stroke of systemic embolism in patients with atrial fibrillation not caused by a heart problem and for treating deep vein thrombosis and pulmonary embolism after 5–10 ten days of anticlotting treatment by injection of infusion. Although one of the primary warnings about Savaysa is increased risk of bleeding (as with any anticlotting agent) in clinical trials, it showed less major bleeding in comparison with warfarin. Primary dosage is 60 mg daily; however,

dosage adjustment may be required for impaired creatinine clearance.

Two antidiarrheal treatments approved for diarrhea-predominant irritable bowel syndrome (IBS-d) include a new drug and a new approved use for a previously approved drug. Viberzi (eluxadoline) is a new oral agent with mixed opioid receptor activity that results in improved stool consistency, reduced pain, and lessened bowel contractions. Common side effects include nausea, abdominal pain, or constipation. Caution should be used with history of chronic constipation, bile duct obstruction, pancreatitis, and severe liver impairment. This is a controlled substance with a recommended dosage of 100 mg twice daily (BID) with meals. Reduced dose (75 mg BID with meals) is recommended in absence of a gallbladder or hepatic impairment or if larger dose is not tolerated. Xifaxan (rifaximin), an antibiotic derived from rifampin, was previously approved at low doses for a short time (200 mg three times a day for 3 days) to treat traveler's diarrhea caused by *Escherichia coli*. New approval for use to treat IBS-d came after continued clinical trials showed that larger doses for longer periods (550 mg three times a day for 14 days) would in many cases reduce the diarrhea caused by IBS-d. Caution, as with rifampin or any rifampin derivative, should be used in presence or history of severe liver impairment.

Recent drug approvals also offer those individuals with plaque psoriasis another option Cosentyx (secukinumab). Psoriasis is a systemic autoimmune disorder and plaque psoriasis (the most common form of psoriasis) causes thick, red patches with silver-white scales on the skin. Cosentyx is an interleukin antagonist that reduces the inflammation associated with the development of the psoriatic plaques. It is injected subcutaneously (not in the areas of redness or in the plaques) and comes in injectable pens or prefilled syringes for patients' home use or in powder for reconstitution and injection by a professional health provider. Like all drugs in this class, it carries warnings related to a compromised immune system: before use the patient should be evaluated for tuberculosis and Crohn's disease and cautioned about reporting any chronic or systemic infections. Most common adverse reactions are upper respiratory tract infection and diarrhea.

The above review provides a brief look at the new drugs approved for a wide variety of health problems. In the following section, discussion focuses on generic drugs: what they are and benefits or challenges associated with generic drugs. Examples of new first-time generic drugs approvals are listed in Table 2.

Generic Drug Approvals

In 1984, patent rules for drugs were changed to allow innovative pharmaceutical companies to more easily patent their generic copies of branded drugs. This change related to patents held on branded drugs and did not change the rigorous FDA standards to which all drugs, brand name and generics, are held. In order for a generic drug to receive FDA approval, it must bioequivalent to the brand name drug; it must be the same in dosage form, safety, strength, route of administration, quality, and efficacy. Generic products must also meet the same manufacturing and packaging standards as those of brand name drugs. However, generic drug manufacturers do not have to repeat the costly animal and clinical research on ingredients or dosage forms already approved for safety and effectiveness. Therefore a generic is generally much less expensive than the counterpart brand named drug. In fact, it is estimated that generic drugs save consumers billions of dollars a year at retail pharmacies and even more billions are saved when hospitals use generics (FDA, 2015c).

As the market for generic drugs increases every year, several different pharmaceutical companies may seek approval for their version of the generic compound at different times; thus, there may be more than one generic copy seeking approval or on the market. Table 2 provides examples of recent first-time generic drug approvals.

Although the increase in bioequivalent generics coming to market may be of economic benefit to consumers, the generic products may also cause some confusion. Generic drugs are marketed under the generic name, whereas brand name drugs carry the proprietary brand name a pharmaceutical company has under patent

Table 2. Examples of First-Time Generic Drug Approvals (January to July, 2015)

Generic Name	Brand Name
Ritonavir tablets	Norvir tablets
Esomeprazole magnesium delayed-release capsules	Nexium delayed-release capsules
Aripiprazole tablets (Alembic Pharmaceuticals)	Abilify tablets
Aripiprazole tablets (Teva Pharmaceuticals)	Abilify tablets
Testosterone topical gel	Androgel
Almotriptan malate tablets	Axert tablets
Bivalirudin for injection	Angiomax injection
Repaglinide and metformin hydrochloride tablets	Prandimet tablets
Linezolid injection	Zyvox injection
Omeprazole magnesium delayed-release tablets (OTC)	Prilosec OTC delayed-release tablets
Linezolid tablets	Zyvox tablets

Note. OTC = over the counter.

(e.g., Abilify vs. arpiprazole). Although generic drugs are in the same form (tablet, capsule, gel, patch, etc.) and dosage as the counterpart brand name, the generic drug may be a different size or color. This can be confusing to anyone who is not aware that the difference between a generic drug and the counterpart brand drug is only differences in name or appearance of the drug and not differences in purpose, strength, efficacy, warnings, cautions, and administration directions.

Conclusion

The information above provides brief descriptions of important new drug approvals and new first-time generic approvals. Informed and knowledgeable nurses are in a position to help patients understand their new drugs, correct misinformation or misunderstandings, and educate patients about the safety cautions for their new drugs. Whether brand name or generic, patient education should include teaching the patient the importance of always reading the drug information that comes with their drug and reinforcing the need to follow the safety guidelines that nurses always follow when administering a medication: right drug, right route, right time, and right dose.

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