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FDA Approves a Wide Range of New Drugs and Biologicals this Quarter

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New Drugs

By Rodney G. Richmond, RPh, MS, CGP, FASCP



FDA Approves a Wide Range of New Drugs and Biologicals this Quarter

Halfway through 2014 it was another productive quarter at the Food and Drug Administration (FDA) with the approval of 11 new molecular or biological entities. Meanwhile, a number of drugs are on-schedule to lose patent protection this year, including Nexium®, Actonel®, Boniva®, Celebrex®, Evista®, Exalgo®, Exforge®, Intuniv®, Nasonex®, Restasis®, and Trilipix™. Making the Rx to Over-the-Counter (OTC) switch so far this year are Nasacort® (allergic rhinitis) and Nexium® (GERD), with Flonase® to follow in 2015.

Controlled-Substances: The Drug Enforcement Administration (DEA) stole the headlines in this category with their rescheduling of all hydrocodone products to Schedule II effective October 6, 2014. Previously, hydrocodone was in Schedule II as a single-entity, but that was of little consequence until the approval of Zohydro™ER since hydrocodone was only available as a combination product. Effective August 18, 2014, tramadol was moved to Schedule IV, something that had been done legislatively in 10 states. Newly approved controlled-substances included: Targiniq™ER (oxycodone/naloxone, C-II), an abuse-deterrent extended-release formulation for severe pain requiring around-the-clock, long-term treatment; Bunavail™ (buprenorphine/naloxone, C-III), a buccal film for maintenance treatment of opioid dependence; and Belsomra® (suvorexant, C-IV) a first-in-class sleep agent. And potentially blazing new trails, sources report the FDA has taken up a DEA request to evaluate the medical evidence related to the safety and effectiveness of marijuana, a move that could result in the drug being “weeded” out of Schedule I.

Diabetes: The insulin market is heating up as biosimilars and newer forms emerge. Basaglar™ (insulin glargine, biosimilar) was tentatively approved, subject to a 30-month stay in the wake of pending patent infringement litigation. Afrezza®, an ultra-rapid acting powder insulin delivered through the whistle-sized Dreamboat inhaler, hopes to succeed where Exubera® failed. Other new diabetic drugs

or indications include Jardiance® (empagliflozin), the third drug approved in its class for adult, type II diabetes, and Eylea® with a new indication for diabetic macular edema. New formulations include Invokamet™ (canagliflozin/metformin) and Levemir® FlexTouch® (pen design).

Infectious Disease: Jublia® (efinaconazole) and Kerydin™ (tavaborole), both first-in-class once-daily antifungal agents, were approved for onychomycosis of the toenails. Jublia® is administered through a built-in flow-through brush applicator, while Kerydin™ is applied with a dropper. Sivextro™ (tedizolid) and Orbactiv™ (oritavancin), fast-tracked as Qualified Infectious Disease Products, are new antibacterial agents approved to treat acute bacterial skin and skin structure infections, including MRSA. Orbactiv™ is given as single-dose while Sivextro™ is 6-day course. Triumeq® was approved as a once-daily, fixed-dose combination of the antivirals dolutegravir, abacavir and lamivudine to treat HIV in adults.

Hematology/Oncology: Zydelig™ (idelalisib) is a much anticipated first-in-class treatment for relapsed chronic lymphocytic leukemia and two types of lymphoma. Zydelig™, granted accelerated approval and designated as a breakthrough therapy and orphan drug, carries a boxed warning and is approved with a Risk Evaluation and Mitigation Strategy. Beleodaq™ (belinostat), also receiving accelerated approval as an orphan drug, is intended to treat peripheral T-cell lymphoma in patients who have relapsed or are refractory to other treatments. Keytruda™ (pembrolizumab) is the first programmed death inhibitor

| Brand Name | New Molecular/Biological Entity | Formulation | Regimen | Estimated Cost |
|------------------------------------|---------------------------------------|-------------|-----------------|-----------------|
| Chronic Care | | | | |
| Belsomra® | Insomnia | Oral | Bedtime | NA |
| Basaglar™ KwikPen® | Diabetes, Insulin glargine biosimilar | SubQ | Once-Daily | \$400/5 pens |
| Jardiance® | Diabetes, Adult Type 2 | Oral | Once-Daily | \$361/month |
| Striverdi® Respimat® | COPD | Inhalation | Once-Daily | \$187/month |
| Infectious Disease | | | | |
| Jublia® | Onychomycosis, Toenails | Topical | Once-Daily | \$538/bottle |
| Kerydin™ | Onychomycosis, Toenails | Topical | Once-Daily | NA |
| Orbactiv™ | Acute Bacterial Skin infections | IV | Single-Dose | NA |
| Sivextro™ | Acute Bacterial Skin infections | IV/Oral | Once-Daily | \$1,700/course |
| Oncology-Specialty Products | | | | |
| Beleodaq™ | Peripheral T-cell Lymphoma | IV | Dosing Schedule | \$36,000/course |
| Cerdelga™ | Gaucher Disease | Oral | BID | \$25,000/month |
| Keytruda™ | Melanoma, advanced unresectable | IV | Dosing Schedule | \$12,500/month |
| Plegicity™ | Multiple Sclerosis | SubQ | Biweekly | \$4,900/month |
| Zydelig™ | Relapsed CLL, Lymphoma | Oral | BID | \$8,640/month |

N/A = Not Available

approved to treat advanced melanoma. Keytruda™ also received accelerated approval with breakthrough therapy and orphan drug designation. Approved for new indications are: Avastin® (bevacizumab) as combination treatment for patients with persistent, recurrent or late-stage, metastatic cervical cancer; and Promacta® (eltrombopag, PO) for severe aplastic anemia that fails to adequately respond to immunosuppressive therapy.

Specialty Drugs: Plegridy™ (peginterferon β-1a), available in pre-filled syringes, was approved for adults with relapsing forms of multiple sclerosis. Plegridy™ is a pegylated formulation of interferon β-1a which extends its half-life and allows for less-frequent dosing. Genzyme received approval for Cerdelga™ (eliglustat) for long-term treatment of Type 1 Gaucher's disease, a rare genetic glucocerebrosidase enzyme deficiency that causes fatty materials to collect in the liver and spleen. Cerdelga™ is a hard gelatin capsule usually taken twice-daily which makes it more convenient than available infusion treatments.

Pulmonary: Striverdi® Respimat® (olodaterol) is another once-daily, long-acting beta agonist bronchodilator inhaler used for maintenance treatment of COPD. Striverdi®, which carries a boxed warning related to the risk of asthma-related death, may produce paradoxical bronchospasm and should not be used for rescue therapy. Arnuity™ Ellipta® (fluticasone) is a once-daily, dry powder corticosteroid inhaler approved as maintenance treatment of asthma in patients aged 12 years and older. §

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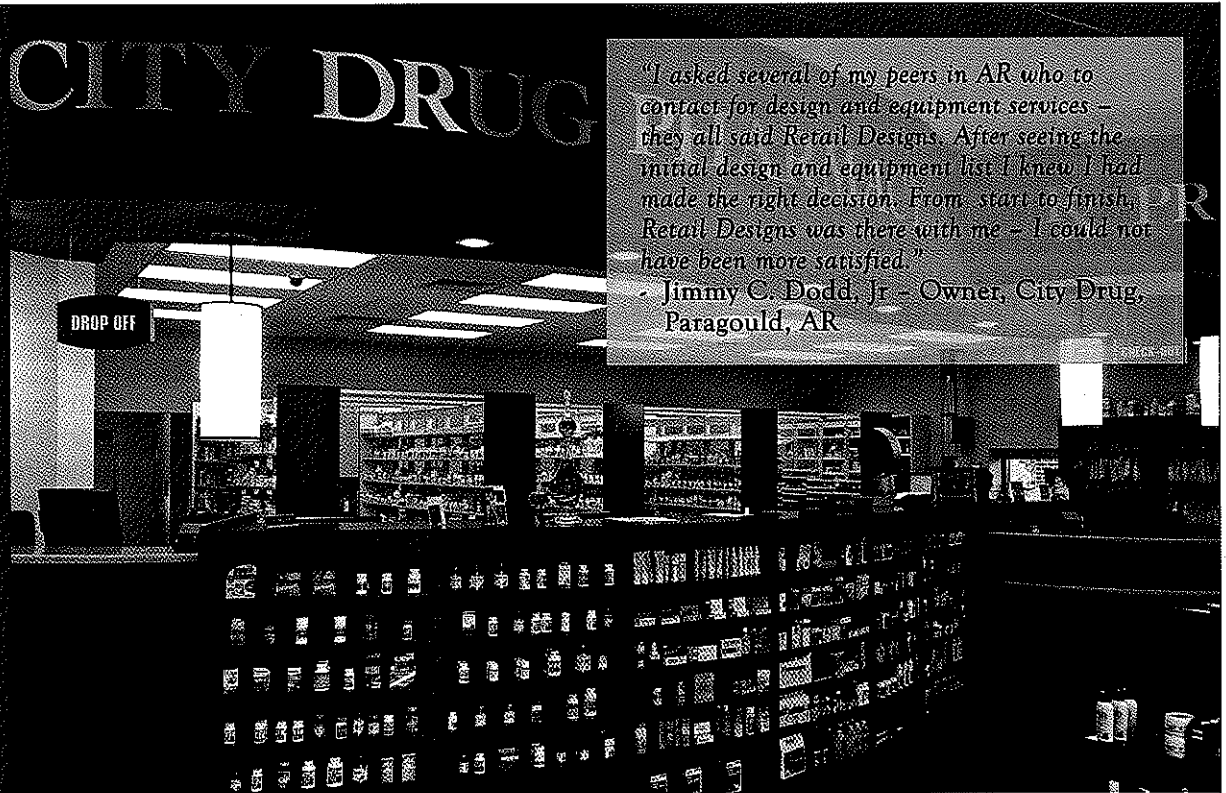
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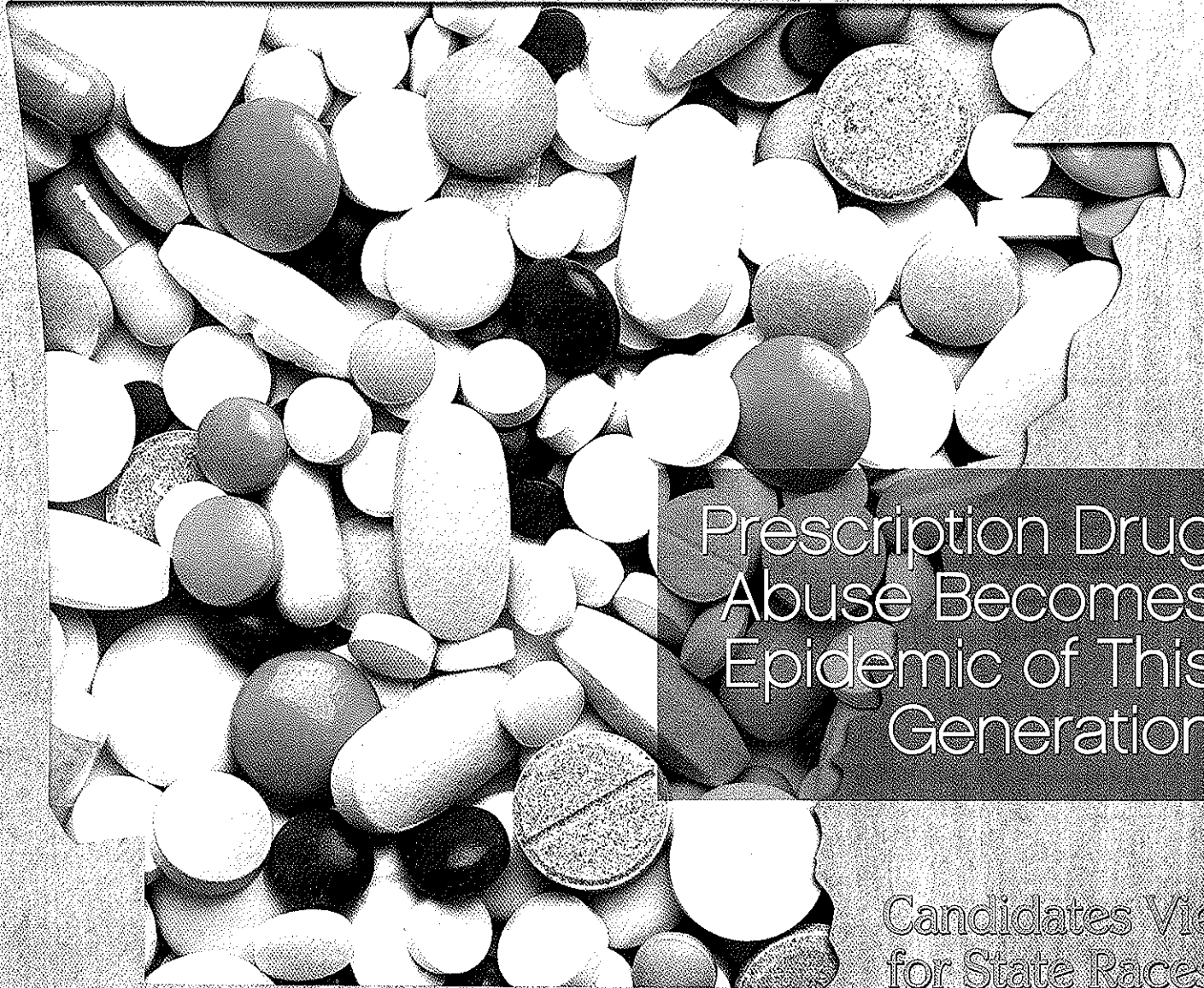
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