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A weekly service from Pharmaceutical Strategies Group.

# MARCH 23, 2017

## GAO To Launch Investigation Of FDA's Orphan Drug Program

Kaiser Health News - March 21

Acting on a request from three influential U.S. senators, the government's accountability arm confirmed that it will investigate potential abuses of the Orphan Drug Act.

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# TRENDING NEWS

## Which PBM best managed drug spending in 2016: CVS Health, Express Scripts, MedImpact, or Prime?

Drug Channels - March 21

Four of the largest pharmacy benefit managers (PBMs)—CVS Health, Express Scripts, MedImpact, and Prime Therapeutics—have raised their swords and released their 2016 drug trend reports.

## One way to force down drug prices: have the U.S. exercise its patent rights

NPR - March 16

Rising drug prices are one of the biggest challenges in health care in the United States. More people are using prescription drugs on a regular basis, and the costs of specialty drugs are rising faster than inflation.

## Business group makes price recommendations for specialty drugs

Drug Topics - March 16

As specialty drugs become more prevalent, the costs associated with them must be lowered, according to a report from the National Business Group on Health (NBGH).

### HHS again delays enforcing 340B drug program

Healthcare Finance - March 21

The U.S. Department of Health and Human Services has again delayed the effective date of enforcing the final rule for the 340B drug pricing program to May 22, and may delay it further to Oct. 1.

### A pricey drug cuts cardiovascular risks in clinical trial — but will insurers cover it?

STAT - March 17

A cholesterol-cutting drug from Amgen succeeded in lowering patients' risk of cardiovascular trouble in a huge clinical trial — but the results, announced Friday, may not be good enough to prompt insurers to cover the expensive drug for millions of patients.

### $89,000 orphan drug gets a new owner — and likely a new price

Kaiser Health News - March 16

After striking a deal Wednesday evening, PTC Therapeutics announced plans early Thursday to buy the Duchenne muscular dystrophy drug Emflaza from Marathon for $140 million in cash and stock. The drug's new price was not announced.

### Anti-PCSK9 drugs: an ingenious solution for a problem that's mostly already solved

Forbes - March 20

On Friday, for the first time, we saw the full data from the FOURIER clinical trial of Amgen's cholesterol-lowering antibody, evolocumab (Repatha).

## FDA NEWS

### Pembrolizumab (KEYTRUDA) for classical Hodgkin lymphoma

FDA - March 14

The U.S. Food and Drug Administration granted accelerated approval to pembrolizumab (KEYTRUDA), Merck and Co., Inc.) for the treatment of adult and pediatric patients with refractory classical Hodgkin lymphoma (cHL), or those who have relapsed after three or more prior lines of therapy.

### FDA approves drug to treat Parkinson's disease

FDA - March 21

The U.S. Food and Drug Administration today approved Xadago (safinamide) tablets as an add-on treatment for patients with Parkinson's disease who are currently taking levodopa/carbidopa and experiencing "off" episodes.

### Adverse event reports rise rapidly even as Trump promises faster drug approvals

FiercePharma - March 20

Even as the new administration is promising to sweep away some FDA practices to speed drugs to market, a new study has found that there has been a dramatic rise in the number of drug side effects reported in recent years.

www.psgconsults.com | 800.687.4404
5360 Legacy Drive, Building 3, Suite 230 | Plano, TX 75024



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