

The World

GPhA Argues that Trans-Pacific Partnership Agreement Will Impede Generic Utilization

WASHINGTON — The Generic Pharmaceutical Association on Wednesday expressed concerns that the current structure of the Trans-Pacific Partnership agreement (TPP) will impede generic utilization and outlined five areas where the agreement could be improved.

TPP is a trade agreement that the United States currently is negotiating with 11 other countries throughout the Asia-Pacific region (Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam).

"The TPP fails to strike the right balance between fostering innovation and ensuring expedited access to more affordable medicines," charged Ralph Neas, GPhA president and CEO, in identifying the first opportunity to improve the trade agreement. "It does too much to extend already generous monopolies enjoyed by brand-name drugs, and too little to ensure that safe, low-cost generic versions are available to patients as soon as legally possible. This is a very serious concern for our industry and for global health."

Neas noted that in the United States, generic utilization has increased to 86% of all prescriptions at only 27% of total prescription costs that has resulted in a \$1.5 trillion savings to the U.S. healthcare system. [Read more](#)

The Nation

FDA Approves Supplemental New Drug Application for the Use of Kalydeco

BOSTON — Vertex Pharmaceuticals has announced that the Food and Drug Administration approved a supplemental new drug application for the use of Kalydeco (ivacaftor) in people with cystic fibrosis ages 6 years and older who have the R117H mutation in the cystic fibrosis transmembrane conductance regulator gene.

The approval follows a recommendation by the FDA's Pulmonary-Allergy Drugs Advisory Committee to approve the medicine in this group of people with CF. Kalydeco is now approved for use in the United States in people ages 6 and older with CF with one of the following 10 mutations: R117H, G551D, G178R, S549N, S549R, G551S, G1244E, S1251N, S1255P or G1349D.

The approval is based on previously announced data from a Phase 3 study of ivacaftor that enrolled 69 people with CF ages 6 years and older who had the R117H mutation. [Read more](#)

CVS Health Expands Scriptability Suite to Mail Service Pharmacy for Blind, Visually Impaired Patients

WOONSOCKET, R.I. — CVS Health is now offering talking prescription labels as well as braille and large print labels through its mail service pharmacy to CVS/caremark members who are blind or visually impaired.

In March [this] year, the company had announced that ScripTalk talking labels were available from

CVS/pharmacy for prescriptions ordered for home delivery through its online pharmacy, CVS.com. Monday's announcement further expands CVS Health's offerings to its blind and visually impaired customers and members.

ScripTalk talking labels, which are part of the company's ScripAbility suite, provide a safe and convenient way to access information on prescription labels for individuals who cannot read standard print. The ScripTalk labels are free to CVS/caremark members who are blind or visually impaired. Members can also obtain a free ScripTalk reader from Envision America that will enable them to listen to the information on the ScripTalk label. [Read more](#)

Big Investments for ACA Innovation Lab, But Most Results Still Pending

The health law's ambitious lab for transforming how medicine is delivered and financed submitted its official report card to Congress on Tuesday, boasting of a few early results but mostly showing many works in progress.

If you're covered by Medicare, Medicaid or even private insurance, there's a decent chance you're part of one of the Department of Health and Human Services' tests to improve care and control costs.

Some 2.5 million patients and more than 60,000 hospitals, clinics and doctors will soon be participating in models run by HHS' Center for Medicare and Medicaid Innovation, the center estimated in its biennial report. [Read more](#)

Insurance Exchange Impacts More Than Just Enrollment Numbers

The biggest payer story of the otherwise light holiday news cycle was the Obama administration's announcement that [roughly 4 million people used either Healthcare.gov or a state insurance exchange to select a health plan in time for Jan. 1 enrollment.](#)

It's certainly a good sign, as it shows that both new and existing consumers remain interested in using the Healthcare.gov insurance exchanges. However, truly judging the impact of the exchanges requires more than just a cursory glance at the numbers. [Read more](#)

UPDATED: FDA Approves Medtronic's Drug-Coated Balloon, Setting Up Clash with Bard in New U.S. Market

The FDA gave PMA approval to Medtronic's ([\\$MDT](#)) IN.PACT Admiral drug-coated balloon for the treatment of [peripheral artery disease](#) in the upper leg, making it a competitor to C.R. Bard's ([\\$BCR](#)) recently approved Lutonix 035 balloon.

"The introduction of drug-coated balloons represents a significant breakthrough that might establish a new standard of care with its potential to change the way we treat peripheral artery disease (PAD) in the leg," said Dr. Michael Jaff of Massachusetts General Hospital. He participated in the device's clinical trials. [Read more](#)

GlySens Gets \$12M Series C For Implantable Continuous Glucose Monitor

GlySens will use a \$12 million Series C financing to conduct a clinical trial for a second iteration of its receiver and implantable sensor that enables [continuous glucose monitoring](#) for diabetic patients. Existing CGM systems typically rely upon a patch-based sensor that uses tiny needles, rather than an implant.

The GlySens system includes an implantable sensor that has been implanted for up to 18 months in preclinical testing. It connects wirelessly to an external receiver. It requires "infrequent" calibration via needle-sticks, unlike most CGMs that often require a twice-daily calibration through a more conventional needle-stick approach, according to the company. [Read more](#)

New Study Sheds Light on Which Seniors are Driving the Rise in Medicare Advantage Enrollment

A new study from the Kaiser Family Foundation counters the popular misperception that the steady rise in Medicare Advantage enrollment has been driven by members of the Baby Boom generation overwhelmingly choosing the private plans as they become eligible for Medicare. Instead, the study finds that a majority of new enrollees in Medicare Advantage in each year were, in fact, seniors switching from traditional Medicare. Less than one-quarter of people newly eligible for Medicare enrolled in Medicare Advantage from the outset, and they comprised less than half of all new Medicare Advantage enrollees each year between 2006 and 2011. Nonetheless, the study, published today in the journal *Health Affairs*, also finds that the *share* of seniors who switch between traditional Medicare and Medicare Advantage is relatively small, reinforcing the notion that most Medicare beneficiaries make a coverage choice and stick with it. [Read the study](#)

Several Affordable Care Act Provisions to Take Effect In 2015

Several provisions of the Affordable Care Act are expiring or taking effect for the first time in 2015, which could pose challenges, *The Hill* reports.

Employer Mandate Kicks In; Some Stakeholders Pressing for Changes

The ACA's employer mandate, after being delayed twice, goes into effect for large companies this year (Ferris, *The Hill*, 1/1).

The employer mandate requires businesses with more than 50 full-time employees working 30 hours or more per week to provide affordable health insurance coverage to workers or face fines.

Under a timeline released by the Department of Treasury and Internal Revenue Service in February, mid-sized businesses that employ 50 to 99 full-time workers will have another year to provide health insurance coverage to employees. These employers will not face fines for failing to provide coverage to workers until 2016, according to the final rule. [Read more](#)

National Events & CE

[Town Hall Conference Call IACP USP <800> January 14, 2014](#)

[IACP Educational Conference \(February 2015\)](#)

[MHA Business Summit \(March 2015\)](#)

[Armada Specialty Pharmacy Summit \(May 2015\)](#)

[Compounders on Capitol Hill \(June 2015\)](#)

Webinar-Top Health Industry Issues of 2015 - Tuesday, January 27, 2015, 2:00 PM ET / 11:00 AM PT

In its annual Top health industry issues report, PwC's Health Research Institute (HRI) explores the top 10 trends that are expected to shape the sector in 2015 including insights from a survey of 1,000 U.S. consumers and interviews with health industry leaders. [No CE will be given, but should be informative webinar] [Register](#)

California

Jones Releases Emergency Rule Over Narrow Provider Networks

On Monday, the California Department of Insurance issued an emergency regulation that aims to address narrow provider networks in the state and improve residents' access to care, Capital Public Radio's "KXJZ News" reports.

Jones announced the new regulation at his second-term inauguration (Moffit, "KXJZ News," Capital Public Radio, 1/5).

For more on the first day of the new legislative session, see today's "Capitol Desk" post.

Background

According to the state Department of Managed Health Care, several insurers, including Anthem, have violated state law by misleading consumers about the size of their provider networks (*California Healthline*, 11/19/14). State Insurance Commissioner Dave Jones (D) said DOI has "received complaints from consumers across the state about long waiting times, about inaccurate directories of providers, about being charged out-of-network costs when there isn't an in-network provider. The list goes on and on and on" ("KXJZ News," Capital Public Radio, 1/5). [Read more](#)

State Legislature Reconvenes Today [January 5]

The state Senate and Assembly reconvene on Monday in Sacramento. Both houses have new leadership and the makeup of both health committees also has changed.

After Monday's meet-and-greet on the legislative floor, lawmakers will need to get down to business pretty quickly. The governor's budget proposal is due Friday, but it could arrive early as it has in past years.

Changes in this year's Legislature include: [Read more](#)

California Health Care Personnel News Roundup for December 2014

California Association of Health Plans

Western Health Advantage CEO Garry Maisel has taken over as chair of the California Association of Health Plans. Maisel will serve as chair for two years. Maisel replaces Blue Shield of California CEO Paul Markovich, who stepped down from the position after a board vote on Dec. 10 (Robertson, *Sacramento Business Journal*, 12/15/14).

California Department of State Hospitals

On Dec. 31, Gov. Jerry Brown (D) appointed Pamela Ahlin as director of the California Department of State Hospitals. The position requires Senate confirmation, and compensation is \$173,349 annually (White, "Capitol Alert," *Sacramento Bee*, 12/31/14).

Brown also appointed Stephanie Clendenin (R) as chief deputy director of DSH. The position requires Senate confirmation, and compensation is \$145,536 annually (*Office of the Governor release*, 12/31/14). [Read more appointments](#)

California Ready to Cope with Rainy-Day Budget Fund

There was never any talk about "Test 3" supplemental appropriations, whether to use marginal or average tax rates to estimate capital gains revenue or other budget speak. Proponents of Proposition 2 on November's

ballot said the measure would compel lawmakers to set aside money to pay off debts and build a rainy-day reserve to “make sure that we don’t repeat this cycle of boom and bust budgeting.”

The simple themes of Proposition 2 proponents’ TV ads and mail pieces will give way in the coming months to the legislative nitty-gritty of implementing a measure that has multiple moving parts and interactions with existing budget laws. The decisions could swing, by billions of dollars, what actually goes into the Proposition 2 reserve or is available for debt repayments. [Read more](#)

California Hospital News Roundup for the Week of January 2, 2015

Daughters of Charity Health System

Some members of the Service Employees International Union-United Healthcare Workers West have announced their support for the sale of six Daughters of Charity Health System hospitals to Prime Healthcare Services, despite the union's campaigning against the sale, according to a statement from the health system.

In a petition, some union members said they support the sale because Prime has pledged to help preserve members' jobs and pensions (Daughters of Charity Health System release, 12/15/14). The sale is pending approval by State Attorney General Kamala Harris (D), who has until Feb. 11 to approve or void the deal (*California Healthline*, 12/12/14).

Hoag Hospital Foundation, Newport Beach

Hoag Hospital Foundation has received a private \$1.5 million donation to support the hospital's stroke program, according to a release from the foundation. [Read more](#)

Relevant California State Department Websites

[CAL MediConnect](#)

[California Department of Health Care Services](#)

[California Department of Insurance](#)

[California Department of Managed Health Care](#)

[California Department of Public Health](#)

[California Department of Workers’ Compensation](#)

[California State Board of Pharmacy](#)

State Net Capitol Journal

News and Views from around the 50 states.

The next issue of Capitol Journal will be published January 12

CA Events & CE

STERILE COMPOUNDING New Laws and Regulations-Western University-March 2015

For more information [click here](#)

West Coast Pharmacy Exchange April 2015

For more information [click here](#)

SEMINAR 2015 (October) [click here](#)

California State Board of Pharmacy

Pharmacists and pharmacy technicians may earn 6 hours of CE for attending the entire day of a board of pharmacy meeting; and 2 hours of CE for each committee meeting. Please go to www.pharmacy.ca.gov for the meeting schedule.

CA Legislation

While the Legislature reconvened the 2014-2015 Legislative session on January 5, 2015, the majority of bills will not be introduced and in print until late February.

You may always learn more information by logging onto www.leginfo.ca.gov