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In This Issue...

- [House Committee Repeals Part of Affordable Care Act](#)
- [House Democrats Send Letter to DEA about Shortages](#)
- [House Member Sends Letter to FDA about Mislabeled Painkillers](#)
- [House Hearings Requested on Medical Devices](#)
- [PCORI Releases Draft Priorities for Research and Research Agenda](#)
- [CDC Updates](#)
- [AHRQ Updates](#)
- [DEA Announces Fourth National Prescription Drug Take-Back Day](#)
- [FDA Sends Congress User Fee Recommendations](#)
- [FDA Updates](#)

Congress

House Committee Repeals Part of Affordable Care Act

On Wednesday January 18, the House Ways and Means Committee approved [H.R. 1173](#), the Fiscal Responsibility and Retirement Security Act of 2011, introduced by Congressman Charles Boustany (R-LA). The legislation repeals the Community Living Assistance Services and Supports program (CLASS Act), which was a long-term care insurance program and part of health care reform legislation.

The Department of Health and Human Services decided to [suspend implementation](#) of the program in October after they were unable to put a program in place that meets the law's requirements of being voluntary, self-sustaining and solvent over 75 years. Pharmacists should note this development as long-term care will grow in importance as the nation's population continues to age.

House Democrats Send Letter to DEA about Shortages

House Energy and Commerce Committee ranking member Henry Waxman (D-CA), Subcommittee ranking members Diana DeGette (D-CO) and Frank Pallone (D-NJ), and Budget Committee Ranking Member Chris Van Hollen (D-MD) sent a [letter](#) to the Drug Enforcement Administration (DEA) about shortages of attention deficit disorder (ADD) drugs.

The quota system is meant to prevent drug abuse by allowing companies to make only the amount of the product expected to be used for medical purposes. Recent news stories report manufacturers are mostly fulfilling their quotas with the brand-name versions of the drugs, leading to shortages of the cheaper, generic options. The letter questioned DEA's claim that plenty of the drugs are available. The lawmakers asked for a full accounting of how the administration sets quotas for different products, how frequently it recalculates quotas and how it establishes quotas for drugs with rapidly increasing sales.

For additional information on the drug shortage issue, visit APhA's [pharmacist.com](#) and [Pharmacy Today](#). See also [FDA](#) and the [American Society of Health-System Pharmacists](#)

01/27 [Applications Due to CMS Innovation Center on Health Care Innovation Challenge](#)

01/31 [Comments to HHS on Essential Health Benefits](#)

02/06 [Applications to CMS on Independence-at-Home Demo](#)

02/13 [Comments to FDA on Drug Literature Review](#)

02/17 [Comments to FDA on Drug Shortage Notification Interim Final Rule](#)

02/17 [Comments to FDA on Professional Labeling](#)

02/21 [Comments to FDA on MedGuide Burdens](#)

03/15 [Comments to PCORI on Draft Agenda](#)

03/27 [Comments to FDA on Uses of Certain Marketed Products](#)

04/12 [FDA Meeting: Role of Naloxone in Opioid Overdose Fatality Prevention](#)

[Join APhA's Advocacy Key Contact \(AAKC\) Network:](#) Get involved with the AAKC network and learn about opportunities to support APhA's advocacy and health care reform implementation efforts.

[Visit the APhA-Political Action Committee \(APhA-PAC\) Web site:](#) The APhA-PAC Web site is your one-stop shop for all information and news on the APhA-PAC.

[Read APhA2011 Issue Briefs:](#) APhA's Government Affairs Team prepared 14 issue briefs covering key legislative and regulatory issues over the past year, including health care

Web sites.

reform (HCR).

Ask questions, share comments with the APhA Government Affairs staff at gvtaff@aphanet.org.

House Member Sends Letter to FDA about Mislabeled Painkillers

Congresswoman Mary Bono Mack (R-CA) sent a [letter](#) to FDA for its failure to issue a recall of mislabeled painkillers. On January 9, [FDA issued a warning](#) to consumers and health care professionals concerning possible safety risks associated with specified opiate products manufactured for Endo Pharmaceuticals by Novartis Consumer Health.

Senior Editor for APhA's Legislative and Regulatory Update: Jason Hansen

Specifically, there is concern surrounding a packaging problem which could result in a tablet or pill being included in a different medication. Bono Mack claims the agency knew about problems at a Novartis manufacturing facility in Nebraska for years but failed to take action until Novartis voluntarily closed its facility and issued a recall for over-the-counter medications in the past few weeks.

While FDA works with these manufacturers on this packaging problem, pharmacists are encouraged to examine opiate medications made by Endo Pharmaceuticals to ensure the tablets are the same. [Specific instructions for dispensing pharmacists](#) to identify wrong tablets from Endo Pharmaceuticals are provided on the FDA'S Web site. [Photographs](#) of the potentially affected products are also provided at <http://www.endo.com/>.

Visit the [FDA Web site](#) for additional information as well as the list of products that may be impacted by this packaging problem.

House Hearings Requested on Medical Devices

House Energy and Commerce top ranking Democrat Henry Waxman (D-CA), Oversight and Investigations Subcommittee ranking member Diana DeGette (D-CO) and committee member John Dingell (D-MI) sent a [letter](#) to Chairman Fred Upton (R-MI) requesting that the committee hold hearings regarding several medical devices. The hearings would take place as the panel prepares to reauthorize the [Prescription Drug User Fee Act \(PDUFA V\)](#) and the [Medical Device User Fee and Modernization Act \(MDUFMA\)](#). The lawmakers are concerned that the committee has not focused enough on certain devices defects and adverse effects or on the potential need to strengthen FDA's regulation of medical devices.

HHS

PCORI Releases Draft Priorities for Research and Research Agenda

On January 23, the Patient-Centered Outcomes Research Institute (PCORI) released its draft [National Priorities for Research and Research Agenda](#). The Agenda's purpose is to guide funding announcements for comparative clinical effectiveness research. Improving Healthcare System Performance is among five areas the draft report identifies as in need of comparative effective research to support decision-making.

Of importance, pharmacists and their role are specifically suggested as an area of research on page 17 of the document:

"Research that compares the effectiveness on patient outcomes of a wide range of system-level strategies to incorporate new and extended roles for allied health professionals (e.g., pharmacists, nurses, physician assistants, dentists, patient navigators, volunteers, etc.) into the healthcare team. (Criteria addressed: Improve Healthcare System Performance)"

APhA is reviewing the Agenda and will comment accordingly. [Comments are due to PCORI](#)

March 15, 2012. We would appreciate your input. Please contact Jason Hansen, APhA's Director of Health Policy, by [email](#) or by phone at 800-237-APhA with your feedback. This is an extremely important and positive development as pharmacists continue to become more fully integrated into the health care team.

CDC Updates

- [Flu Activity & Surveillance](#)
- [Morbidity and Mortality Weekly Report \(MMWR\)](#)
- [State Mandates on Immunization and Vaccine-Preventable Diseases](#)

AHRQ Updates

- [AHRQ 2011 Annual Conference: Slide Presentations](#)
- [Study Finds E-prescribing Is Safe and Efficient, but Barriers Remain](#)

DEA

DEA Announces Fourth National Prescription Drug Take-Back Day

DEA announced another [National Prescription Drug Take-Back Day](#) for Saturday, April 28, 2012, from 10:00 am - 2:00 pm. The Take-Back Day is intended to provide a setting for individuals who want to dispose of unwanted and unused prescription drugs.

DEA's Drug Take-Back Days are meant to improve public health and safety through keeping prescription drugs out of the hands of teens and others. DEA reports that previous Drug Take-Back Days in 2010 and 2011 collected nearly 500 tons of drugs. DEA has posted specific state contact information on its Web site. More information will be available in the near future on collection locations. Pharmacists are encouraged to share information about the upcoming Drug Take-Back Day with their patients and work with their local law enforcement to help increase awareness of such events in their community.

See [DEA's Web site](#) for more information on this upcoming event. In addition, visit the [SMARxT Disposal Web site](#) for more information on drug disposal.

FDA

FDA Sends Congress User Fee Recommendations

On January 13, [FDA announced](#) it completed recommendations for three user fee programs. HHS Secretary Kathleen Sebelius sent the recommendations to Congress the same day as the announcement. The three programs include the fifth authorization of the Prescription Drug User Fee Act (PDUFA V), as well as new user fee programs for generic drugs and biological products.

The user fees are paid by manufacturers ("users") to help fund FDA's drug approval process and support about half of FDA's operating budget; the other half comes from Congressional appropriations. FDA's PDUFA V recommendations include [improvements to REMS](#) that APhA supports and advocated for at FDA's public hearing in November 2011. For more information, read our [pharmacist.com article](#).

FDA Updates

- [MedWatch](#) Safety Announcements
- Guidance for Industry
 - [Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling](#)
- Draft Guidance for Industry
 - [Product-Specific Bioequivalence Recommendations](#)
- [Current Drug Shortages](#)
- [Drug Recalls](#)
- [New and Generic Drug Approvals](#)
- [FDA Drug Info Rounds](#)
- [Upcoming FDA Meetings](#)
- [Medication Guides](#) (updated)

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