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Top Stories

**CHPA applauds the progress of the Dextromethorphan Distribution Act**

CHPA issued a [press release](http://www.chpa-info.org/web/newsletter/archive/2009/03_06_09_XNL.html) March 4 giving its support to H.R. 1259, the "Dextromethorphan Distribution Act," which was introduced March 3 in the U.S. Congress by U.S. Representatives Fred Upton (R-Mich.) and Rick Larsen (D-Wash.). The bill, passed by the U.S. House Committee on Energy and Commerce the following day, seeks to allow the sale of raw dextromethorphan, an active ingredient commonly found in OTC cough medicines, only to legitimate entities registered with FDA or state agencies. This legislation comes after a number of instances of teenagers purchasing the potent ingredient online and abusing it with tragic consequences.

"CHPA commends Congressmen Upton and Larsen on the leadership they have shown on this important issue," said CHPA's Linda Suydam. Because CHPA has been a longtime supporter of keeping the raw, unfinished form of dextromethorphan out of teenagers' hands, the association is a staunch advocate of the bill. "We believe that it will help protect America's youth from unscrupulous online pushers who knowingly provide kids with the raw form of this ingredient as a means to get high," stated Suydam.

This is the third time the Dextromethorphan Distribution Act has been introduced in the U.S. Congress. It passed the U.S. House of Representatives twice, but failed to move forward before the close of both the 109th and 110th Congresses. "We fervently hope that the third time's the charm for this important measure to get passed into law and start protecting our nation's children," said Suydam.

CHPA has taken a comprehensive approach to preventing the abuse of dextromethorphan in any form by working with a number of partners on educational programs and integrating all of the association's initiatives on StopMedicineAbuse.org. Suydam says that CHPA's efforts are already making progress. "Two preeminent teen surveys released over the last three months show either a slight decline in abuse rates or rates that have remained flat," she said ([See related story](http://www.chpa-info.org/web/newsletter/archive/2009/03_06_09_XNL.html)). "That news encourages us and tells us that we are making a difference through our education efforts, but we have more work to do."

CHPA contact: Mimi Pappas | [Back to the top](http://www.chpa-info.org/web/newsletter/archive/2009/03_06_09_XNL.html)

**GAO believes FDA should take further actions to improve dietary supplement oversight**

The U.S. Government Accountability Office (GAO) released a report March 2 entitled [Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding](http://www.chpa-info.org/web/newsletter/archive/2009/03_06_09_XNL.html). The report, which was prepared in...
response to a request by U.S. Representatives Henry Waxman (D-Calif.) and Bart Stupak (D-Wisc.), made a number of recommendations including:

- The U.S. Department of Health and Human Services (HHS) and FDA should request authority to require manufacturers to identify themselves as a dietary supplement company as part of existing registration requirements and list all dietary supplements they produce with copies of product labels.
- In addition to the existing requirement that manufacturers report serious adverse events related to dietary supplements, HHS and FDA should request authority to require manufacturers to report minor and moderate adverse events, as well.
- FDA should clarify new dietary ingredient requirements or procedures through guidance.
- FDA should provide guidance to clarify when products should be marketed as either dietary supplements or foods with added dietary ingredients.
- FDA should engage in more consumer outreach on “safety, efficacy, and labeling of dietary supplements.”

CHPA does not believe mandatory reporting of minor or moderate adverse events would be helpful to the agency. As FDA pointed out in its response to a draft of the GAO study, “Although receiving all adverse events on dietary supplements could theoretically enhance our ability to detect signals...we are uncertain whether, in practice, such information would advance the agency’s ability to identify unsafe dietary supplements or to do so quickly. For example, an unintended outcome of receiving such reports might be that the huge increase in minor adverse events might make it more difficult to filter out signals of potential toxicity generated by reports of serious adverse events...”

The report also points to a need for additional resources for FDA. CHPA applauds the call for additional resources for the agency and agrees that guidance on new dietary ingredient requirements would be useful. The association submitted comments on a draft guidance on the subject (See February 18, 2005, XNL), and discussed the importance of guidance in meetings with FDA. The association will continue to work to provide input to the agency as it considers the report’s recommendations.

CHPA contact: Dr. Marcia Howard | Back to the top

New Partnership for a Drug-Free America 20th annual study shows progress in teens recognizing dangers of OTC cough medicine abuse

CHPA issued a press release February 26 announcing that a new study released by the Partnership for a Drug-Free America offers some promising news regarding teens and the abuse of OTC cough medicines. According to the 20th annual Partnership Attitude Tracking Survey (PATS), a national study of teen behavior and attitudes about drugs and alcohol, an increased number of teens view the intentional abuse of OTC cough medicines as risky. PATS indicates 48 percent of teens now understand this abuse is dangerous, up
CHPA's Communications department. "We welcome this new data as a signal that the efforts of the leading makers of over-the-counter cough medicines in past years is making a difference," remarked CHPA's Linda Suydam. Lifetime abuse rates among teens for OTC cough medicines has not increased from previous PATS data and has remained relatively flat over the past few years: 10 percent, or roughly 2.4 million teens, report ever having abused an OTC cough medicine to get high. Federal research released in December 2008 shows a slight overall decrease in annual OTC abuse rates among teens (See December 12, 2008, XNL). "More teens seeing the abuse of cough medicine as dangerous is a very positive indication," said the Partnership for a Drug-Free America's Steve Pasierb. "And, while the study shows that 37 percent of teens reported learning a lot about the risk of drug abuse from their parents—a significant 16 percent increase from the previous year—too many parents are still missing crucial opportunities to talk about the intentional abuse of medicines."

Research shows that teens who learn a lot about drugs from their parents are up to half as likely to abuse drugs. The important role that parents play in helping shape their children's attitudes is not lost on CHPA. "With the help of such partners as the Partnership for a Drug-Free America, the Community Anti-Drug Coalitions of America, and D.A.R.E. America, we will continue our efforts to make sure all parents are aware of this substance abuse behavior and talk with their children about it," said Suydam.

All of CHPA's efforts to fight teen medicine abuse are located at StopMedicineAbuse.org (See related story).

CHPA contacts: Virginia Cox and Mimi Pappas | Back to the top

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StopMedicineAbuse.org gets a new look and purpose

StopMedicineAbuse.org, CHPA’s web site providing parents and communities with the tools to combat the abuse of cough and cold medicine by teens, has been revamped to bring together the association’s collective resources under one comprehensive, dynamic roof.
In conjunction with the site launch, the association is unveiling its new community page on Facebook. This page will allow CHPA to reach and educate its audiences and stakeholders directly in an interactive, engaging way. More and more parents are joining social networks to stay in touch with friends and family, as well as to keep track of their teens. In fact, according to recent research, the number of adults with a social network profile has quadrupled in the last four years. With so many parents on these networks, the association hopes that bringing its initiative to Facebook will help parents easily inform their friends, loved ones, and colleagues about medicine abuse and the online resources accessible through StopMedicineAbuse.org.

CHPA also has integrated its Five Moms campaign and Dose of Prevention Toolkit into this new web site to build a comprehensive product representing all of its interests, audiences, partnerships, and programs.

CHPA contact: Virginia Cox | Back to the top

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**Federal Register Update**

**OTC skin protectant astringent monograph amended**

FDA issued a final rule in the March 6 Federal Register that makes technical amendments to the final monograph for OTC skin protectant astringent drug products. The final rule adds the generally recognized as safe and effective (GRAS/E) combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate in powder or tablet dosage form to produce a 0.13 to 0.5 percent aluminum acetate solution when the powder or tablet is dissolved in the amount of water indicated in the "Directions" section of the Drug Facts label.

The technical amendment also includes additional labeling requirements for OTC astringent drug products that consist of this GRAS/E combination. FDA provided a sample OTC astringent drug product label in its Federal Register notice as an illustration for manufacturers.

FDA notes that the agency has amended the final monograph in response to a
FDA advisory committee to discuss draft risk communication plan

FDA published a notice in the March 5 Federal Register announcing that its Risk Communication Advisory Committee will meet April 30 from 8:00 a.m. to 5:00 p.m., and May 1 from 8:00 a.m. to 2:00 p.m., at FDA's Rockville, Maryland, facility. The purpose of the one-and-a-half day public meeting is for the committee to discuss FDA's draft risk communication strategic plan and to provide recommendations on strategic priorities for research on effective risk communication.

Requests to make oral presentations and written submissions are due by April 23.

AHRQ seeks comments on proposed study on knowledge and use of acetaminophen

The U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ) issued a notice in the February 26 Federal Register announcing its proposed data collection for a qualitative study to identify issues that relate to the misuse and overdosing of OTC acetaminophen. The proposed study will be administered by AHRQ through the University of Pennsylvania and in consultation with FDA.

According to AHRQ, the proposed study has two goals. The first goal is to qualitatively explore knowledge, attitudes, beliefs, and practices regarding adult and adolescent self-administration of OTC acetaminophen, as well as administration of OTC acetaminophen to children by parents. The second goal is to qualitatively explore the experiences and practices of doctors and pharmacists in communicating the administration and risks of OTC acetaminophen to patients and consumers.

Comments are due by April 27.

OMB asks for input on improving the process and principles governing regulation

The Office of Management and Budget (OMB) published a notice in the February 26 Federal Register inviting the public to provide comments to assist the agency in the development of recommendations to President Barack Obama for a new executive order on federal regulatory review. OMB was instructed to prepare the recommendations in a January 30 presidential memo (See February 6 XNL).

While public input is typically not sought for executive orders, OMB is opening up the process due to the high level of interest in the issue. The agency notes that while it will seriously consider the comments it receives on the principles and procedures governing regulatory review, it will not provide responses.
Meetings

CHPA's 2009 Annual Executive Conference kicks off next week

In less than one week, CHPA's membership will be convening at The Ritz-Carlton Golf Resort in Naples, Florida, for the association's much-anticipated Annual Executive Conference (AEC). If you are a CHPA member and have not yet registered for the 2009 AEC, there is still time to join your industry colleagues at what is sure to be one of the business highlights of the year.

Under the theme “Healthcare Highway: Connecting with the Consumer Mindset,” AEC sessions—provided by Hearst Magazines, Information Resources, Inc., Catalina Marketing, Parade Publications Inc., and The Nielsen Company—will look at this topic from a variety of perspectives. From an economic outlook to the state of the industry, from maintaining informed consumers to navigating for success, attendees will hear it all first hand at CHPA's flagship event.

CHPA sponsors

CHPA thanks all of the member companies that are sponsoring events. Your support is key to the AEC's success.
Get your global passport to growth and innovation at CHPA's 2009 Regulatory & Scientific Conference

CHPA's 2009 Regulatory & Scientific Conference (RSC), set for May 7-8 at the Gaylord National Resort & Convention Center in National Harbor, Maryland, will provide attendees with an introspective look into some of the leading issues surrounding the global OTC industry. Expert speakers will address a number of relevant issues at the conference including open innovation and its impact on...
the future, the international regulatory environment, new avenues for Rx-to-OTC switch, and external factors impacting innovation.

The RSC also will feature representatives from FDA's Center for Drug Evaluation and Research and the Center for Food Safety and Applied Nutrition who will brief attendees on the status of current programs and future activities. Additionally, a closing panel on policy and politics will be opened up for audience questions.

**New additions to the RSC program**

CHPA is pleased to announce that three new speakers have been added to the RSC's already impressive roster. Kevin Smith, CVS/pharmacy (retired), and Annie Weisbrod, The Procter & Gamble Company, will serve on the panel on external factors impacting innovation. Peter Barton Hutt, Covington & Burling, will participate in the closing session on policy and politics.

**CHPA members are encouraged to register by March 26**

CHPA members are reminded to register for the RSC by March 26 to receive a $75 discount. Program and registration information for all participants is available at [chpa-info.org](http://www.chpa-info.org). Please note that the CHPA room block at the Gaylord will end April 22, or sooner, if it is filled. Be sure to mention CHPA to receive the discounted room rate.

**RSC Sponsors**

*CHPA thanks the following companies that are serving as sponsors for the 2009 RSC:*

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- Schering-Plough HealthCare Products, Inc.
- The Procter & Gamble Company
- Wyeth Consumer Healthcare

**Register today**

Don’t miss the opportunity to learn about issues facing regulators and OTC industry personnel in the U.S. and abroad. Register for the 2009 RSC today at [chpa-info.org](http://www.chpa-info.org).
**Are you holding September 16-17 for CHPA's 2009 Market Exchange?**

CHPA members are encouraged to keep September 16-17 free to attend the association’s 2009 Market Exchange at the Hyatt Regency New Brunswick in New Jersey. This is the essential opportunity of the year to meet face-to-face with the people you need to see. Mark your calendars today.

Additional details on CHPA's 2009 Market Exchange will be provided in future issues of the *Executive Newsletter*.

**CHPA announces plans for the 2009 Business Development Conference**

CHPA is happy to report that Walgreen Co. will serve as the retail immersion partner for the association’s 2009 Business Development Conference. The conference will be held October 27-28 at The Westin Chicago North Shore in Wheeling, Illinois, just outside of Chicago. An exciting day-and-a-half is being planned, so members are asked to make a notation in their calendars. More information on the 2009 Business Development Conference will be provided in the coming months.

**In Brief**

**CHPA celebrates a new addition**

CHPA is pleased to report that Jackson Sapp Funderburk made his grand debut Tuesday, February 24, weighing in at 6 pounds, 12 ounces. Proud mother Elizabeth Funderburk, CHPA's director, communications & media relations, and father John are happily enjoying their new role as first-time parents.