Top Stories

Five Moms urge more parents to keep teens from abusing cough medicine

CHPA issued a press release May 6 commemorating the one-year anniversary of the launch of the Five Moms: Stopping Cough Medicine Abuse campaign. This ongoing grassroots effort, launched by CHPA in May 2007, features five extraordinary mothers from across the country who are working to bridge the communication gap between parents and teens about the dangers of abusing cough medicine. To date, the campaign has reached more than 23 million parents through various Internet channels including personal blogs, an online messaging system, advertising, and a "viral" video.

"The process to address cough medicine abuse is twofold," said CHPA President Linda Suydam. "First, we had to raise awareness among parents that teens abusing cough medicine was a reality. Now, with our growing community of engaged parents, we are asking our Five Moms members to engage in an open communication with their teens to help prevent this type of substance abuse."

The mothers at the heart of the Five Moms campaign are Julie Bermant, a pediatric nurse practitioner from Massachusetts; Blaise Brooks, an accountant from California; Christy Crandell, a California mother of a former cough medicine abuser; Becky Dyer, a D.A.R.E. officer and deputy sheriff from Kansas; and Hilda Morales, an educator from Texas. The women have posted the following steps on the web site, FiveMoms.com, to help all parents open the door to conversations with their kids about cough medicine abuse:

Five Moms: Stopping Cough Medicine Abuse

Julie Bermant
Blaise Brooks
Christy Crandell
Becky Dyer
Hilda Morales
November

17-18 FDA's Risk Communication Advisory Committee Meeting

December

2 FDA's Food Advisory Committee Meeting

● Educate yourself,
● Safeguard medicines at home,
● Communicate with your teen,
● Monitor Internet usage, and
● Recognize signs your teen may be abusing cough medicine.

"Like so many parents out there, I can't help but think how different my family's life would be had we known that cough medicine abuse was happening and we were armed with information on how to prevent it," said Five Mom Christy Crandell, whose son was arrested for armed robbery while high on cough medicine and marijuana. "I can only hope that other parents understand the importance of taking these steps to protect their teens from abusing cough medicine."

The Five Moms campaign is getting the word out to parents that cough medicine abuse is happening in homes across the nation, and that the Internet is a driving force.

Since the debut of the campaign in May 2007:

● More than 84,000 people have visited FiveMoms.com, a web site where parents can find information about cough medicine abuse, read blog entries from the Five Moms, and link to sites that have additional resources for fighting cough medicine abuse.
● Site visitors have sent almost 130,000 "Tell-A-Friend" e-mails, alerting other parents to the information available on FiveMoms.com.
● The Five Moms viral video has been viewed by more than 13,000 people on YouTube, Google video, and Yahoo! video.

"Our members have worked tirelessly to educate parents about the potential for abuse," said Suydam. "The success of the Five Moms campaign has taken this effort to an entirely new level."

CHPA contact: Elizabeth Funderburk | Back to the top

The 2008 RSC focuses on enhancing consumer healthcare through innovation

CHPA's annual Regulatory & Scientific Conference (RSC) was held May 8-9 in Washington, D.C. This year's RSC explored innovations in policy, technology, and communication that can be used to facilitate and improve consumer self-care. RSC Planning Committee Chair Sue James, GlaxoSmithKline, presided over the conference and CHPA Scientific Affairs Committee Chair Barbara Kochanowski, The Procter & Gamble Company, presented the status of the regulatory community report. The event was attended by more than 150 people and over 25 FDA representatives.
CHPA Executive Newsletter

RSC Planning Committee Chair Sue James, GlaxoSmithKline, who presided over the RSC, provided attendees with a general overview of the conference.

Burrus reveals the top trends in healthcare

Keynote speaker Daniel Burrus, Burrus Research Associates, started the RSC off on a high note by delivering a thought-provoking presentation on strategic leadership. He challenged attendees to think optimistically about the future and not dwell on existing problems, so that challenges that lie ahead are viewed as opportunities, not obstacles. Burrus also stressed the importance of communicating with consumers in a two-way interaction, instead of simply providing one-way information. According to Burrus, the current top healthcare trends include genetic screening, prevention, remote diagnostics, the virtual hospital, e-enabling healthcare, evidence-based medicines, and results-based funding. He also predicted that the future of healthcare will be focused on relationships built on trust as well as technological changes. But Burrus also noted that motivation is the key to drive people towards technology, especially in a multi-generational population.

Examining challenges and opportunities in the healthcare environment

In a session chaired by John Dent, John Dent Consulting, the current consumer healthcare environment was examined from various perspectives. That session panel featured Dr. Charles Ganley, FDA's Office of Nonprescription Products (ONP); Ed Kuffner, McNeil Consumer Healthcare; Hubertus Cranz, Association of the European Self-Medication Industry (AESGP); Catherine Polley, Food Marketing Institute; and Aaron Morel, Yankelovich.

During his remarks, Ganley discussed some of FDA's challenges concerning advisory committee meetings. Two such challenges, he said, are the recruitment of appropriate committee members who comply with the strict conflict of interest provisions and the timely circulation of voluminous briefing material to all parties prior to a meeting. Ganley stated that, in the future, the agency intends to include information on general OTC background in briefing packages and to allow more time for the committee members to review the material.

Kuffner recapped a number of positive industry initiatives in 2007. At the top of his list was FDA's acceptance of CHPA as a sponsor at advisory committee meetings on OTC monograph ingredients, thereby enabling the industry to provide scientific data in a joint and coordinated manner.
Shifting the focus overseas, Cranz provided an overview of the latest regulatory developments in the European Union (EU). He explained that while decisions about advertising and Rx-to-OTC switches have not yet been harmonized between EU Member States, progress has been made. OTC medicines are now eligible for the centralized procedure and the new European Medicines Agency guideline on invented names clarifies policies on OTC names across the EU.

Rounding out the morning session were Polley and Morel. Polley discussed the important role pharmacists can play as advisors at the point of OTC sale, while Morel advised the industry to develop easy-to-use tools to aid consumers in selecting the most appropriate OTC products to meet their needs.

Following a break in the RSC program, Dr. Bill Cooley of Cooley Consulting, Inc., musically summons attendees into the session.

Taking novel approaches to packaging

The afternoon session on packaging innovations was chaired by Luis Salmun, Schering-Plough Healthcare Products. Included on the panel were Edward Bauer, Packaging & Technology Integrated Solutions; Mike Fien, Comar; Michael Doran, Rivet Digital; Michael Levy, FDA's Office of Compliance; and Michael Labson, Covington & Burling.

Bauer opened the session with a discussion of some of the new developments in this area broken down by packaging categories. Some of the examples he cited include bottles with dispensing closures for solid-dose forms, blister cards for one day of use, and unit dose liquids. Bauer added that more complex new packaging solutions could have integrated audible and visual alarms or could be connected to databases.

Fien focused his attention specifically to plastic liquid dosing devices. Dosing accuracy and child resistance are well-known challenges and Fien explained that innovative devices, such as press-in bottle adapters or audible click oral dispensers, offer solutions to these challenges.

Michael Doran complemented both Bauer's and Fien's remarks by providing examples of intelligent tools that allow consumers to make better decisions at the point of sale. One such example he showed was an interactive kiosk with a touch screen on hair colorants used to find an individual's ideal product. This type of
technology could potentially be used for OTC products.

Levy and Labson closed the session on new packaging and dispensing solutions. Levy reminded the industry that dosage delivery systems must be in line with product labeling and showed examples of poorly designed dosing devices. Labson explained that new tools, like the kiosk Doran displayed, could potentially fall under medical device requirements. He also described the conditions under which the secondary packaging, as opposed to the primary packaging, can have the child-resistant packaging element.

**Understanding what all the buzz is about**

Julie Aker, Concentrics Research, introduced two speakers in the third session, who illustrated novel marketing strategies to capture the consumer and ensure a successful product launch. Steve Burton, GlaxoSmithKline, and Adam Paulisick, Neilsen Online, each discussed innovative ways of understanding what consumers are thinking.

Burton commented on the elaborate instruction and coaching embedded in GlaxoSmithKline's advertising program to promote the safe use of and appropriate decisionmaking regarding the new OTC switch drug alli™. The addition of this supplemental educational material promoted an overall behavior change and outlook on eating and living healthy: alli™ is more than a pill; it is an entire program. According to Burton, by "thinking outside of the box" in its advertising, GlaxoSmithKline was able to build consumer trust before the product was even on the market.

Paulisick encouraged the audience to reach out to consumers in unconventional methods. He stressed the importance of consumer-generated media to the industry, noting that there are currently 79 million communities and social networks on the Internet. Many of these communities, said Paulisick, reveal consumer evaluations, concerns, and questions regarding OTC products and product use which could be captured as a tool for promotion and feedback collection.
Scientific Affairs Committee Member
Leonard Baum, Bayer Healthcare LLC
Consumer Care, describes some of the forthcoming challenges to the OTC industry as well as the numerous opportunities that exist.

Looking at FDA's past and future

Participating in the FDA panel at the RSC were Leah Christl, Joel Schifferbauer, and M. Scott Furness, all from the agency's Office of Nonprescription Products (ONP). They discussed some of FDA's past and future initiatives and provided an update on anticipated changes in the agency's employee structure. The group also highlighted some of FDA's most notable activities of the past year and projected upcoming regulations and documents.

From right: Sue James of GlaxoSmithKline listens as FDA's Joel Schifferbauer, Scott Furness, and Leah Christl provide an update on the agency's activities.

Zeroing in on the biggest consumer healthcare issue

Douglas Bierer, Douglas Bierer Consulting, LLC, moderated the RSC's most diverse panel. Experts from various fields each provided their perspectives on what they consider to be the most important aspect of consumer health healthcare, including James Appleby, American Pharmacists Association; Andrea Leonard-Segal, FDA; David Spangler, CHPA; Minnie Baylor-Henry, McNeil Consumer Healthcare; and Lee Rucker, AARP.

Appleby led the discussion with an inspiring declaration for transformation and promoted collaboration in modifying the consumer selection process of OTC
products in pharmacies.

Leonard-Segal said that the relationships made between government, associations, and companies were of the utmost importance for developing trust and providing safe and effective products for our consumers. She also spoke to the significance of educating consumers on the proper use of OTCs.

In his comments, Spangler cited three important issues: 1) the missing opportunities in linking self-diagnosing devices to OTCs, 2) new technology and providing consumers with both "high-tech and high-touch" opportunities, and 3) the movement towards electronic health records.

Baylor-Henry agreed with Spangler on the value of providing choice while offering information on products in retail stores through interactive technology such as kiosks. She added that it is necessary for the industry to “stop looking backwards and look to ahead.”

Rucker closed out the panel session with a novel recommendation to OTC manufacturers. She suggested that companies include medication records in OTC product packages and also to make the records available online.

Fielding audience questions (from right) were: James Appleby, APhA; Andrea Leonard-Segal, FDA; David Spangler, CHPA; Minnie Baylor-Henry, McNeil; and Lee Rucker, AARP.

CHPA thanks the following generous sponsors of the 2008 Regulatory & Scientific Conference:
CHPA thanks RSC Planning Committee Chair Sue James and the other committee members for the excellent program.

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

**CHPA encourages companies to lend assistance to China**

With a death toll of over 20,000 and still rising, and with hundreds of thousands displaced from their homes following this week’s earthquake in the Sichuan Province in China, CHPA President Dr. Linda Suydam reached out to the association's members to draw additional attention to the humanitarian crisis and the need for assistance. “I know that all of your companies seek to provide aid and support in times of crisis, both domestic and international,” wrote Suydam. “This week, many of our eyes are on China.”

Suydam explained to members that friends and industry colleagues in China helped to illuminate the magnitude of these events in the most human of terms by pointing out that "It's a very little village, the frail earth. It's a much greater power, the global industry."

"With their personal call for support," concluded Suydam, "I urge you to provide needed medicines through such organizations as AmeriCares, the International Federation of Red Cross and Red Crescent Societies, or others."

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**Federal Register Update**

FDA schedules meeting to discuss pilot program on proposed proprietary
FDA issued a **notice** in the May 12 *Federal Register* announcing that its Center for Drug Evaluation and Research and its Center for Biologics Evaluation and Research are conducting a public meeting to prepare for a pilot program that will enable pharmaceutical manufacturers to evaluate proposed proprietary names and to submit the data generated from those evaluations for FDA's review. The meeting will be held June 5-6 from 8:30 a.m. to 5:00 p.m. at the Crowne Plaza Hotel in Silver Spring, Maryland.

FDA states that reducing the potential for medication errors due to proprietary name confusion is part of the agency's ongoing product risk management effort. As part of its performance goals, the agency agreed to publish a concept paper and implement a pilot program that will provide a consistent, scientific approach to the review of proprietary names data.

During the two-day meeting, the agency intends to discuss a draft concept paper that describes the details of the pilot program, examine the proposed recommendations for conducting a proprietary name review, and disclose its plans for reviewing submissions from the pilot program. FDA notes that the draft concept paper will be made available on its web site prior to the meeting. The agency plans to formally issue the concept paper by the end of fiscal year (FY) 2008 and to begin enrollment in the pilot program sometime in FY 2009.

Requests to make oral presentations at the meeting should be sent to FDA's Lana Pauls by May 23. Comments on the draft concept paper and pilot program are due by July 27.

CHPA contact: David Spangler | Back to the top

**FDA's Science Board to meet this month**

FDA issued a **notice** in the May 8 *Federal Register* announcing that its Science Board will meet May 30 from 8:00 a.m. to 3:30 p.m. at the Washington D.C. North/Gaithersburg Hilton in Gaithersburg, Maryland. According to FDA, the Science Board is meeting to hear a subcommittee review of the National Center for Toxicological Research and Office of Regulatory Affairs, discuss ways to keep pace with technical and scientific evolutions in the fields of regulatory science, and receive an update on the agency's science programs and infrastructure.

Requests to make oral presentations at the meeting should be submitted to FDA's Carlos Peña by May 15. Written submissions are due by May 23. FDA recommends that interested parties check the agency's web site for updates and the agenda for this meeting.

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**FDA seeks comments on draft PDUFA IV drug safety plan**

FDA issued a **notice** in the May 5 *Federal Register* seeking public comments on a draft document entitled *Prescription Drug User Fee Act (PDUFA) IV Drug Safety Five-Year Plan*. The document describes FDA's strategy for meeting the commitments for enhancing and updating the draft safety system within the PDUFA.
IV program.

Written requests for copies of the draft plan should be sent to FDA's Office of Executive Programs, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Bldg. 51, Room 6100, Silver Spring, Maryland 20993-0002. FDA is requiring all interested parties to include one self-addressed adhesive label to help process requests.

Comments on the PDUFA IV drug safety plan are due by June 19.

FDA holds annual regulatory affairs conference in California

FDA published a notice in the May 5 Federal Register announcing that the agency, along with the Orange County Regulatory Affairs Discussion Group, is cosponsoring the 11th annual regulatory affairs educational conference. The event will be held June 11-12 in Irvine, California.

The purpose of the conference is to provide industry representatives with the chance to meet face-to-face with FDA reviewers and compliance officers from the agency's centers and district offices. During the two-day, interactive meeting, speakers will focus on product approval, compliance, and risk management issues surrounding the drug, device, and biologics industries.

Additional information and registration materials for the conference are available online.

Government agencies publish semi-annual regulatory agenda

The Unified Agenda of Regulatory and Deregulatory Actions was published in the Federal Register May 5 and posted to www.reginfo.gov. The items listed are rough projections of what certain government agencies, including FDA, hope to publish in the Federal Register over the next 12 months.

The following are some issues of interest to the industry:

U.S. Food and Drug Administration
For a copy of the U.S. Department of Health and Human Services' agenda, click here and select the appropriate agency.

• Proposed rule on electronic data submission requirements for NDAs: 10/08
• Proposed rule on Rx and OTC combination policy: 9/08
• Proposed rule on electronic submission of postmarketing safety reports: 10/08
• Final action on changes to drug establishment listing and registration, including NDC changes and electronic submission: 12/08
• Final action on safety reporting requirements, revisions: 4/09
• Final action on complete response letters on NDAs: 7/08
• Final action on dietary supplement good manufacturing practices and 100 percent identity testing exemptions: 6/08 (an interim final rule was issued 6/07)

• Final action on toll-free number for adverse event reporting of NDA drugs: 12/08 (an interim final rule was issued 1/08)

• Final action on prior notice of imported food under the Bioterrorism Act: 8/08 (an interim final rule has been in place since 10/03)

• Final action on cochineal extract and carmine allergen labeling for foods and cosmetics: 5/08

• Final action on cattle-derived materials in medical products, recordkeeping: 6/09

• Final action on good manufacturing practice amendments: 12/08 (a direct final rule was withdrawn 4/08; a companion proposed rule remains in place)

• Final action on good manufacturing practices cut label controls, amendment: to be determined

OTC Review-related:

Certain Category II and III ingredients
• Proposed rule on making ingredients not GRAS/E: 6/08

Stimulants
• Proposed rule on hangover claims, amendment: 4/09

Topical antimicrobials
• Proposed rule on food handlers: 12/08

Bronchodilators
• Final action on ephedrine single ingredient, amendment: 1/09

Cough/cold combination products
• Final action on bronchodilator/expectorant combinations: 3/09

Cough/cold decongestants
• Final action on phenylpropanolamine, amendment: to be determined

Antihistamines
• Final action on claims, amendment: 5/09

Internal analgesics
• Final action on internal analgesics: 3/09
• Final action on required warnings and other labeling: 3/09
• Proposed rule on combinations with sodium bicarbonate, amendment: 4/09
• Proposed rule on overindulgence/hangover, amendment: 4/09
• Proposed rule on miscellaneous issues, amendment: 5/09
• Proposed rule on pediatric, amendment: to be determined

Convenience size products
• Final action on labeling: 3/09

Overindulgence products
• Final action on bismuth subsalicylate: 4/09
• Final action on antacids: 4/09
Ozone-depleting substances
• Final action of removal of epinephrine’s essential-use determination: 10/08

External analgesics
• Proposed rule, amendment: 5/09
• Final action on GRAS/E dosage forms for patches: 5/09

Laxatives
• Proposed rule on professional labeling: to be determined
• Final action: to be determined

Ophthalmic products
• Final action on emergency first aid eye washes, amendment: to be determined

Oral healthcare products
• Proposed rule on plaque and gingivitis: to be determined

Skin protectants
• Final action on diaper rash: 5/09
• Final action on aluminum acetate, technical amendment: 5/09
• Final action on fever blisters and cold sores: to be determined

Sunscreens
• Proposed rule on time and extent: 5/09
• Final action on Ultraviolet A and Ultraviolet B: 5/09
• Proposed rule on insect repellent: to be determined

Vaginal contraceptives
• Proposed rule: 5/09

Weight control products
• Final action on phenylpropanolamine: to be determined

Skin bleaching products
• Final action on hydroquinone: 5/09

Antidiarrheals
• Proposed rule: to be determined

Poison treatments
• Proposed rule on ipecac: 5/09

Urinary analgesics
• Proposed rule: 5/09

Acne products
• Final action on benzoyl peroxide: 5/09

U.S. Drug Enforcement Administration

For a copy of the U.S. Department of Justice’s agenda, click here and select the appropriate agency.

• Final action on ephedrine, pseudoephedrine, phenylpropanolamine chain of distribution, importer information: 12/08

• Final action on Combat Meth Act self-certification by regulated sellers of listed chemicals: 10/08 (an interim final rule was issued 9/06)

• Final action on Combat Meth Act transfers following import and export: 8/08 (an interim final rule was issued 4/07 with a temporary stay on certain
provisions since 5/07)
• Final action on Combat Meth Act import quotas: 8/08 (an interim final rule was issued 7/07)
• Final action on Combat Meth Act List I location registration: 12/08
• Final action on Combat Meth Act threshold removal: 1/09
• Final action on Combat Meth Act fee for self-certifiers: 11/08
• Final action on Combat Meth Act certification recordkeeping requirements: 12/08
• Final action on precursor chemical security requirements: to be determined

CHPA contact: David Spangler | Back to the top

Meetings

Register today for CHPA’s 2008 Market Exchange

Members are urged to register today for CHPA's 2008 Market Exchange to ensure that their company is included on the list that table hosts may choose from in scheduling appointments. Registration materials for Market Exchange are available online.

Questions About Market Exchange?

For appointments and sponsorship information, contact CHPA's Phyllis Taylor (202.429.3549)

For all other inquiries, contact CHPA's Kass Kassouf (202.429.3544) or Maria Sarabia (202.429.3545)
Thank you, sponsors

CHPA thanks the following member companies that have generously agreed to serve as Market Exchange sponsors:

- CPL•Contract Pharmaceuticals Ltd.
- Country Living
- The Emerson Group
- Good Housekeeping
- Mars OTC/DTC
- WebMD

If you are interested in learning more about Market Exchange sponsorship opportunities, contact CHPA's Phyllis Taylor.

CHPA News

CHPA comments on FDA’s ANPR for food labeling

CHPA filed a submission with FDA April 30 on the agency's advanced notice of proposed rulemaking (ANPR) regarding revisions to food labeling reference values and mandatory nutrients. In the ANPR, FDA sought comments on whether daily values (DV's) should be set based on estimated average requirements (EARs) for those nutrients for which an EAR has been set, or if DVs should be set based on recommended dietary allowances (RDAs). Additionally, the agency asked for input on whether DVs should be based on population-coverage or population-weighted EARs or RDAs.

In its submission, CHPA strongly recommended that the DVs continue to be based on RDAs, not on EARs. Furthermore, these DVs should be determined based on population-coverage RDAs, as opposed to population-weighted RDAs. For those nutrients without an EAR, the association stated that DVs should be based on population-coverage adequate intakes.

To support its recommendations, CHPA added that this approach would:

- Provide appropriate guidance on nutritional requirements to the greatest number of consumers;
- Minimize possible consumer confusion about the meaning and proper use of DVs due to potential changes in the label values;
- Lessen the need for re-education of consumers, teachers, and healthcare
professionals if the DVs were modified based on changes to standard-setting procedures; and

- Maintain public confidence in the ability of FDA and industry to appropriately interpret, utilize, and convey the best scientific data on nutrition.

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

In Brief

AmeriCares makes an appeal for donations for cyclone and earthquake victims

AmeriCares has responded to disasters around the world for over 25 years to deliver critical medicines and medical supplies that help restore health and save lives of people in crisis. The nonprofit organization has been working around the clock to respond to the cyclone in Myanmar and the 7.9 earthquake in the Sichuan Province of China.

"AmeriCares is working to secure all necessary approvals and flight clearances for delivery of essential supplies, including antibiotics, multivitamins, and medicines to treat diarrheal diseases, malaria, and dengue fever, as well as water purification sachets," said Curt Welling, president and chief executive officer of AmeriCares.

How companies can help

AmeriCares is seeking donations of the following medicines and medical supplies to support our emergency response efforts:

**Myanmar cyclone victims**

*(Accepting into Stamford, Connecticut, warehouse)*

- Topical antibiotics
- Topical disinfectants
- Bismuth subsalicylate/GI preparations
- Analgesics
- Oral rehydration salts
- Vitamins
- Ophthalmic solutions
- Asthma inhalers

**China earthquake victims**

*(Locally sourced from within China)*

- Analgesics and anesthetics
- IV solutions
- Skin disinfectants and dressings
Companies interested in making product donations should contact AmeriCares’ Lauri Fogarty-Swenson (203.658.9526). Financial contributions can be made at www.americares.org.

AmeriCares to participate in CHPA’s 2008 Market Exchange

Representatives from AmeriCares will be participating in CHPA’s 2008 Market Exchange, scheduled for September 17-18 in New Brunswick, New Jersey (See related article). CHPA members that would like to set up an appointment to meet with AmeriCares to learn more about the organization’s efforts should contact CHPA’s Phyllis Taylor.