



HEALTHCARE COMPLIANCE PACKAGING COUNCIL
IMPROVING PATIENT ADHERENCE AND OUTCOMES THROUGH PACKAGING



July 2013

HCPC would like to thank our member sponsors
for this edition of RxAdherence News:

Winpak, Constantia Flexibles, MWV and RockTenn

Save the Date for the HCPC Annual Fall Members Meeting

The HCPC Annual Fall Members Meeting always proves to be an opportunity to gain industry insight with valuable speakers and presentations. Please plan to join us in early November 2013. Our valued member, Honeywell, has again graciously offered to host this meeting. More information on the complete agenda will be provided as it develops.

Date: Tuesday, November 12
Tentative Time: 8:30 - 4
Larry Bossidy Learning Center
Honeywell
101 Columbia Road
Morristown, NJ 07962

[Gear Up for this year's Compliance Package of the Year Competition Entries accepted September 15, 2013 – February 28, 2014](#)

Each year the HCPC solicits entries from the pharmaceutical industry for consideration in its *Compliance Package of the Year* competition to determine pharmaceutical packages best designed to optimize patient adherence. Qualifying packages for the Compliance Package of the Year category must:

- 1) Be in a compliance-prompting format with at least one patient adherence assistance

Industry News

- > [Letter from the Board](#)
- > [Letter from the Executive Director](#)
- > [HCPC Re-releases its Whitepaper in a new, easier to read format](#)
- > [HCPC Provides Formal Response to FDA's Draft Guidance for Industry](#)
- > [FDA announces grant funds for medication adherence campaign](#)
- > [CVS Caremark Study Compares Adherence Metrics](#)
- > [FDA Shuts Down Over 1,600 Online Pharmacies](#)
- > [Get ready for Pack Expo 2013!](#)
- > [Member News](#)

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Letter from the HCPC Board

Hello, RxAdherence Readers. I hope everyone is enjoying the Summer and taking some well-deserved vacation time with family. So far, it's been a busy summer for the HCPC.

It was great to see so many HCPC members and other patient adherence packaging advocates at the recent Pharmapack 2013 in Philadelphia. We trust the show was a successful event for everyone and that you all had the opportunity to pick up our revamped HCPC Whitepaper, Improving Medication Adherence Through Packaging. This well-received synopsis of the multiple adherence packaging studies has been re-released with images of leading examples of packaging specifically designed to improve medication adherence. These images will better allow those not fully familiar with this packaging concept to understand how useful calendarized packaging can be. If you were

not able to pick up your copy at Pharmapack, please see the article referencing this Whitepaper in this issue of RxAdherence News for a direct link to the paper.

Also, on your behalf, the HCPC submitted a formal response to the FDA's Request for Comments on Draft Guidance for Industry on Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors. We appreciate those members who were instrumental in shaping the draft with us. A copy of the formal response is available from our website and through a link provided in this RxAdherence News issue. We hope to further engage the FDA in the recognition of compliance-prompting/calendarized packaging as an extremely successful patient adherence tool.

While at Pharmapack, the HCPC Board met to discuss some of our ongoing initiatives, as well as plan our upcoming Annual Fall Members meeting. Part of our preparation will include members of the HCPC Board calling our member liaisons to determine what the HCPC can do to better serve its members while pursuing our mission to improve patient/medication adherence through the increased use of compliance-prompting packaging. Please anticipate a call in the coming months from one of your HCPC Board members. In advance, we thank you for your time, your opinion and suggestions.

Please note I must close this letter with some very sad news that I heard while writing this letter to you. Our newest HCPC Board member, Ken Sadler, of Legacy Packaging passed away a few days ago. Ken was the Chief Operating Officer at Legacy and was instrumental in moving our organization's current blister research project into an actual action plan. Ken was a highly qualified chemical engineer with a unique background in the FDA-regulated industry for more than twenty four years. Prior to working for Legacy, Ken was the Vice President of Compliance at International Labs in St. Petersburg, FL, as well as being the VP of Quality and Operations for American Softgel Products in Las Vegas. Our condolences go out to Ken's family, his business colleagues and his friends. Ken's fervor, energy and knowledge will be missed.

Best Personal Regards,
Ralph Mendoza,
HCPC Board Chairman 2013-2014

feature

- 2) Have been commercially available during 2013
- 3) Not require drug products to be repackaged by patients.

There is also an Innovative Design category for non-commercially available compliance-prompting packaging formats. Qualifying entries for this category must include patient adherence features and also not require repackaging by consumers. There is no fee to participate. For more information, please visit

<http://www.hcpconline.org/compliance-package.html>.

RxADHERENCE STRATEGIES TO IMPROVE PATIENT OUTCOMES 2013

Even though it was several weeks ago, the presentations from RxAdherence 2013 are still quite relevant to today's patient adherence market. The many informative presentations from this industry leading conference are available for download.

[Click here](#) for access to these useful presentations on the impacts of improving patient adherence!

Membership Information

The HCPC offers its members a "voice" in pharmaceutical packaging issues and the opportunity to help promote the many benefits of patient compliance packaging. From suppliers of pharmaceutical packaging components, to machinery manufacturers, to contract packagers, to industry consultants and experts, our members share the mission of promoting broader adoption of compliance-prompting packaging to improve patient outcomes. Become a member of this dynamic organization today!

HCPC Sponsor



Today's finest
blister foil solutions



Letter from the Executive Director

Hello RxAdherence Readers, Hope you are enjoying your Summer! For those of you on the East Coast, yes, it is Summer, although you may need to consult your calendar to prove it!

In May, you read about HCPC's opportunity to testify before a Congressional Committee regarding supply chain security legislation and HR 1919. A parallel version of that is now moving through the Senate, S957, and is equally important for pharmaceutical manufacturers and all of us working in and around the supply chain. It is not clear if the Senate version will be ready for a vote before they break for recess. If it follows that path of other contentious issues, I doubt it will see a vote in the next weeks.

While not directly related to compliance prompting packaging, I believe it is important to this cause because it will increase the likelihood that manufacturers' original packaging could reach the patient and that is a basic point for CPP, elimination of repackaging in the pharmacy.

More recently, HCPC has provided comment on FDA's Draft Guidance for Industry on Safety Considerations for Container Labels and Carton Labeling to Minimize Medication Errors, Docket No. FDA-2013-D-0401. (<http://www.regulations.gov/%23!documentDetail;D=FDA-2013-D-0401-0010>)

While HCPC agreed with the majority of the Guidance, we also feel that there is too much of a negative tone toward calendarization and other features intended to improve health outcomes.

The HCPC certainly understands the Agency's need to caution that proper application of calendar features and, in truth, any compliance feature, is critical and the industry needs to employ them properly. We disagree, however, with the way these features are framed. In particular on page 16 lines 606-609, the agency has a dismissive tone toward "special packaging" implying that they "might" be helpful. Well, no, they have been proven to be helpful over and over again as even noted several times in the IOM 2006 report Preventing Medication Errors and supported again in our whitepaper (<http://www.hcpconline.org/whitepaper.php>). It seems the Agency is suggesting that the rare exceptions where problems have occurred make this style of packaging less desirable, but fails to note that current vial and bottle packaging results in \$290 billion in loss due to medication errors! Working together to properly employ these modern features would be a dramatic improvement over the status quo.

The guidance suggests "larger container labels or unique packaging to accommodate all critical information" for a drug. We think this is a definite need and is consistent with the goals of the HCPC. This flies directly in the face of current, yet antiquated, pharmacy packaging which is dominated by the amber vial. The guidance fails to note that these improvements they suggest will only be helpful if they reach the patient!

Rather than throw stones, we'd prefer to see the agency work with industry to develop guidelines for smarter packaging and labeling that could eliminate the potential confusion cited in their draft. We would like to pursue collaborative development for industry, and, more importantly for the patient. There are so many good tools out there and our current model of prescription distribution is so badly broken that any efforts to modify it should be embraced. It will be our task, HCPC staff and members, to reach out and seek an audience with the appropriate FDA staff to engage for the purpose of developing guidelines that will enhance rather than inhibit use of the tools the industry has been developing for more than 50 years. Not only will this effort result in improved medication adherence and improved health outcomes but, it will aid in supply chain security by providing original manufacturers' packaging. This, in turn, will eliminate the opportunity for the introduction of counterfeit, diverted, returned or outdated drugs in pharmacy. The time for dramatic change in pharmaceutical distribution and prescription packaging is upon us. The emergence of supply chain security, desperately sought improvements in health outcomes and now this FDA guidance seeking safer labeling all point to the same conclusion. Better packaging can aid all aspects of the pharmaceutical supply chain from manufacturer through pharmacy to the patient. We simply need to get out of its' way.

A proven foundation for building
successful adherence programs



HCPC Re-releases its Whitepaper in a new, easier to read format

The HCPC Whitepaper, *Improving Medication Adherence with Packaging*, has been improved with the use of product imagery and information on actual compliance-prompting packaging to better illustrate this packaging to those stakeholders outside of the industry. A picture is worth a thousand words, as the saying goes. The images used were HCPC Compliance Package of the Year winners.

Visit

<http://www.hcpconline.org/whitepaper.php>

to receive your latest copy. Please share this whitepaper with your colleagues and customers. We think you will like the new

format.

HCPC Sponsor



HCPC Provides Formal Response to FDA's Draft Guidance for Industry on Safety Considerations for Container Labels and Carton Labeling to Minimize Medication Errors, Docket No. FDA-2013-D-0401

In late June, the HCPC, on behalf of our members, responded to the FDA's request for comments on its Draft Guidance for Industry on Safety Considerations for Container Labels and Carton Labeling to Minimize Medication Errors, Docket No. FDA-2013-D-0401. While we heralded the request, we were concerned about some of the negative comments in the draft surrounding special packaging and calendarized blisters. The FDA Draft Guidance was issued in response to suggested steps by the Institute of Medicine in its Preventing Medication Errors report, 2006/2007. The Draft was issued in response to the IOM's suggested steps in this report, i.e., "The FDA should develop two guidance documents for industry: one for drug naming and another for labeling and packaging. The FDA and industry should collaborate to develop (1) a common drug nomenclature that standardizes abbreviations, acronyms, and terms to the extent possible, and (2) methods of applying failure modes and effects analysis to labeling and packaging." Item #2 resulted in this current draft from the FDA. What the FDA may have missed was provided further in the report. The IOM report goes on to state, "**The FDA, the pharmaceutical industry, and other stakeholders should collaborate to**

develop a strategy for expanding unit-of-use packaging for consumers to new therapeutic areas. Studies should be undertaken to evaluate different unit-of-use packaging and design approaches that will best support various consumer groups in their medication self-management.”

This suggested collaboration is in response to the IOM's discovery that **“Unit-of-use packaging—containers that provide enough medication for a particular period, such as blister packs containing 30 individually wrapped doses—is not widely employed in the United States but is used extensively elsewhere. This form of packaging brings important safety and usage benefits. The committee believes the expanded implementation of unit-of-use packaging in this country warrants further investigation.”**

It is with this positive outlook that the HCPC will seek engagement with the FDA and other stakeholders, including those who also responded to the FDA's request for comments including NCPPIE (National Council for Patient Information and Education), ISMP (Institute for Safe Medication Practices), HDMA (Healthcare Distribution Management Association), NCL (National Consumer League) and many leading pharmaceutical manufacturers, to increase the use of medication adherence packaging. For a copy of the HCPC's formal response, please visit <http://www.regulations.gov/%23!documentDetail;D=FDA-2013-D-0401-0010>

Food and Drug Administration announces grant funds for ‘Script Your Future’ medication adherence campaign

The FDA has touted its pursuit of improved patient adherence by again providing grant funds to The National Consumers League, the nation's pioneering consumer and worker advocacy organization, for the NCL's *Script Your Future campaign*. The multi-year groundbreaking national campaign (www.ScriptYourFuture.org) aims to raise awareness among consumers, family caregivers, and health care professionals about the importance of medication adherence. Nearly three out of four Americans do not take their medication as directed; one out of three people never fill their prescriptions. Poor medication adherence results in 125,000 deaths per year. Improving adherence could save \$290 billion in unnecessary health care costs.

The recent Federal Register announcement that the FDA has committed to support the continued efforts of *Script Your Future* is welcome news to the campaign's 130 Committed Partners, including the HCPC. The grant will assist in the development of new online resources, provide additional support for counseling and consumer education, and increase awareness and understanding of medication adherence. [Read More...](#)

CVS Caremark Study Compares Adherence Metrics By State and Region

This year's 2013 State of the States Report from the CVS Caremark Pharmacy Care Research Institute provides specific information about adherence across three distinct market segments – Health Plans, Employers, and Medicare Part D. The report is meant as a tool to help inform health care, academic and government audiences as they review health care cost drivers and consider factors that can influence adherence across different populations. The growth of the aging population and the increasing prevalence of chronic disease makes the issue of nonadherence an even more critical one for the health care community to solve.

The data presented in the report pages tells an important story about adherence across the United States. First, across all population groups (Health Plans, Employers and Medicare), patients with depression generally had the lowest adherence rates while patients with hypertension were most adherent.

Second, Medicare beneficiaries had the highest adherence rates across the three groups. Third, regional variations were apparent across the groups. Finally, the report also includes information about potential state-by-state cost-savings opportunities if certain adherence measures were improved to optimal levels. For a copy of the CVS Caremark Study, [click here](#).

FDA Shuts Down Over 1,600 Online Pharmacies

06/28/2013

FDA Shuts Down Over 1,600 Online Pharmacies
[Legal Monitor Worldwide]
Published Date: June 28, 2013 08:45:35 AM EDT

An international crackdown on dangerous medications has resulted in the closure of more than 1,600 online pharmacies. The Food and Drug Administration said in a statement Thursday that it took action against more than 9,600 websites in total and seized more than \$41 million worth of illegal medicines. "Illegal online pharmacies put American consumers' health at risk by selling potentially dangerous products. This is an ongoing battle in the United States and abroad, and the FDA will continue its criminal law enforcement and regulatory efforts," said John Roth, director of the FDA's Office of Criminal Investigations.

The effort called "Operation Pangea VI," which involved the FDA, INTERPOL and other international medical and enforcement organizations, resulted in the closure of 1,677 illegal pharmacy websites between June 18 and June 25 this year. The agency calls it the largest Internet-based enforcement action of its kind. [Read More...](#)

Get ready for Pack Expo 2013!



Pack Expo 2013 will prove to be the place to be in September, particularly in the Pharmaceutical Pavilion, where attendees can meet suppliers who are dedicated to answering the unique safety and security challenges pharmaceutical and medical device companies face. Meet your colleagues in The Rx Lounge. Located in the Central Hall. Endorsed by the International Society of Pharmaceutical Engineering (ISPE).

Look for these HCPC Members exhibiting at Pack Expo in September. While there, look for the HCPC Compliance Package of the Year Awards on display in the Showcase of Packaging Innovations!

IMA – Booth 2300
Klöckner Pentaplast – Booth 6011
Körber Medipak NA Inc. – Booth 4717
Mylan – Booth 7189
Perfecseal, a Bemis Co. – Booth 558
RockTenn – Booth 1123
Uhlmann Packaging Systems LP – Booth 4503
Winpak – Booth 2227

For more information on Pack Expo 2013, visit the following link:
http://my.packexpo.com/2013/Public/nz_Login.aspx

Kevin H. Kerchner Named CEO of Aphenia Pharma Solutions

Philadelphia-based Aphenia Pharma Solutions, Inc., a leading pharmaceutical manufacturer and packaging provider in the United States, is pleased to announce Kevin H. Kerchner as its CEO.

Mr. Kerchner brings to Aphenia a track record of accomplishments at companies ranging from Fortune 500 companies to private equity-backed companies. His focus is on team development, improving margins and revenue growth. [Read More...](#)

Digital Hive Mind Contracted by Packaging Coordinators Inc. for Brand Strategy

Packaging Coordinators Inc. (PCI) has contracted Digital Hive Mind to develop and implement a brand strategy with the goal of providing a unified identity for the company's numerous facilities across the US and Europe. Included in the initial phase of the project is a redesigned website, www.pciservices.com, which went live on June 24th. "We have been very pleased with vision and creativity Digital Hive Mind has provided as we develop our evolving marketing strategy. Our new website helps communicate our position as a global industry leader in pharmaceutical packaging, with flexibility to quickly adapt to our changing market. The user navigation and architecture is well thought out. Our experience with the content – managed functionality that the site provides has been very positive, allowing us to make changes real-time as well as accommodate future growth," said Justin Schroeder, Senior Director of Marketing and Development Services for PCI. [Read More...](#)

Packaging Coordinators Inc (PCI) Announces Capital Investment in Rockford Facilities Leading Pharmaceutical Packaging Firm Investing in Support of Business Growth

Packaging Coordinators Inc. (PCI), the leading pharmaceutical contract packaging firm in the United States, is investing in its Rockford facilities. In support of business growth and expansion. The company acquired AndersonBrecon Inc. in May of this year and is adding additional equipment capacity and facilities infrastructure through capital investment, as well as hiring in support of business growth. The company provides packaging services for pharmaceutical and healthcare products, working with leading Pharmaceutical and Biotech companies to bring lifesaving medicines to patients. PCI operates 9 facilities in the greater Rockford, Illinois area totaling over 1 million square feet and employing over 1,300 highly trained associates. PCI is owned by an entity formed by affiliates of lead investor Frazier Healthcare, a leading provider of growth equity and venture capital to high growth and emerging healthcare service and Biotech companies. [Read More...](#)

Bilcare Research Hires Don Sobocinski as Vice President of Sales & Marketing,

Company Also Promotes Two Other High-level Executives: Thomas McDonough and John Zripko

Bilcare Research Inc., one of the world's largest manufacturers of blister packaging solutions, has hired industry veteran Don Sobocinski as its new Vice President of Sales & Marketing. The addition of Mr. Sobocinski comes in tandem with the promotion of two other corporate executives: Thomas McDonough has been promoted to Executive Vice President, and John Zripko has become the company's President. [Read More...](#)

Keystone Folding Box Co. and Information Mediary Corporation Introduce New Electronic Compliance Monitoring Blister Pack

Keystone Folding Box Company, a manufacturer of paperboard packaging

solutions, has collaborated with sensor and printed electronics provider Information Mediary Corporation to develop a “smart” blister package with many of the sustainability benefits of Ecoslide-RX®. The new Ecoslide-RX® with integrated Med-ic® technology made its debut April 21 at the 2013 Global Clinical Supplies Conference in New Mexico. The package is senior friendly and child-resistant. [Read More...](#)

Ecoslide-RX from Keystone Folding Box Co. Wins Two Awards for Compliance-Enhancing Design the AmeriStar Award from the Institute of Packaging Professionals, and First Runner-up in HCPC-Europe’s Columbus Award

Keystone Folding Box Co., a manufacturer of paperboard packaging solutions, has won the 2013 AmeriStar Award for Pharmaceutical Packaging from the Institute of Packaging Professionals (IoPP) for the company’s innovative Ecoslide-RX sustainable compliance package. Ecoslide-RX also was first runner-up for the 2013 Columbus Award for Compliance Enhancing Packaging Design, which is bestowed by the Healthcare Compliance Packaging Council of Europe (HCPC-Europe).

Named for its designation as the most eco-friendly product of its kind on the market, Ecoslide-RX is a child-resistant (F=1), senior-friendly compliance package made from 100% recyclable material. Ecoslide-RX contains no plastic in its secondary packaging and, unlike other paperboard compliance packs, requires minimal film and foil while maintaining the highest-possible child-resistance rating.

Recently, Ecoslide-RX was adopted by Walmart as a compliance package for use in the retailer’s popular \$4 prescription drug program. [Read More...](#)

Rondo-Pak Hires Brooks Durham as Director of Operations, Folding Cartons Manufacturer Also Promotes Edward Bani to Technical Service Manager for Sales

Rondo-Pak, a leading provider of quality folding cartons to the pharmaceutical, biotech and medical device industries, has hired Brooks Durham as its new Director of Operations. A packaging industry veteran with a record of driving profits by improving operations, generating efficiencies and reducing costs, Mr. Durham brings to Rondo-Pak proven strengths in developing process infrastructures across multiple locations; sourcing and negotiating favorable pricing terms while building supplier relationships; and building and developing high performance teams. In addition to bringing in Mr. Durham, Rondo-Pak also has promoted Edward Bani to Technical Service Manager/Sales. [Read More...](#)

Rexam Healthcare Readies Clic-Loc 4 For 2013 Launch

Rexam Healthcare will launch the latest version of its industry reference child resistant closure (CRC) – the Clic-Loc 4 – later this year, in anticipation of the rapid, worldwide growth in demand for oral dose packaging protection. Rexam’s Clic-Loc is the first and only CRC available to combine more than 40 years of demonstrated safe and effective oral dose protection, adult-friendly operation, and multiple manufacturer benefits. The Clic-Loc delivers superior ergonomics, is easily used on production lines, and creates an audible warning click to alert parents and caregivers, the company said in a press release. The new Clic-Loc 4 will provide enhanced functionality and aesthetics, for industry-leading protection, production efficiency and product differentiation. For example, it is designed with a wider application torque window and offers enhanced decoration, the company said. [Read More...](#)

Constantia Flexibles Invests in \$12 Million Expansion of South Carolina Facility

Constantia Flexibles, a global corporation that develops, manufactures and supplies flexible packaging solutions for the pharmaceutical, healthcare, food

and beverage markets – has announced plans to invest \$12 million to expand its main U.S. manufacturing facility in Blythewood, South Carolina. Slated for completion in autumn of this year, the project will add 15,000 square feet of factory floor space to house several new pieces of packaging equipment and more than a dozen new employees.

The Blythewood facility manufactures custom packaging for the pharmaceutical and food industries, including packaging foils for blister packages, child-resistant packaging, and lids for portion controlled containers. The factory also houses equipment used for laminating, coating, rotogravure printing and slitting services. [Read More...](#)

MWV Healthcare Receives Walmart Responsibility Award for Total Health and Wellness

MeadWestvaco Corporation, a global leader in packaging and packaging solutions, received Walmart's "Responsibility Award for Total Health and Wellness," which recognizes MWV's development of the Shellpak® Renew medication adherence solution.

Shellpak Renew was launched in June 2012 to provide an improved and more sustainable medication adherence package for prescription medicines. This type of packaging is proven to help improve patient medication adherence. Better adherence can lead to better patient health.

Shellpak Renew was developed based on feedback from pharmacists and patients. The outer carton is made of MWV's Natralock®, an environmentally-friendly, paperboard-based solution that maximizes the use of recyclable materials and is tear-resistant for a high level of child resistance. The new sustainable and easy-to-use Shellpak Renew is 40 percent smaller and 30 percent lighter than the original Shellpak®, and eliminates the use of plastic. This enhances the sustainability profile, minimizes pharmacy shelf space and improves convenience for patients. To improve adherence, Shellpak Renew includes an integrated calendar for patients to track their doses of medication. [Read More...](#)

Want News? Send it to us!
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