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Global Trends in Child-Resistant Pharmaceutical Packaging

Proven Strategies for Preventing Injury

Honeywell

Abstract

A leading cause of childhood poisoning globally is from accidental ingestion of pharmaceutical drugs, including over-the-counter (OTC) and prescription medicines. Prevention efforts must extend beyond the expectation that parents and caregivers keep medicines locked away. Prevention must also make it difficult for children to open pharmaceutical packages in the first place and if they do, enable access to only a limited number of non-threatening doses.

Since the 1970s, child-resistant packaging (CRP) has proven to be an effective strategy for reducing injury and death. In fact, CRP regulations in the U.S. have served as a platform for regulatory activity in other countries while stimulating a wide range of innovative packaging solutions, including blister pack advances. Such solutions must not only meet country-specific needs for child resistance and senior-friendly package entry, but also respond to constantly changing forces in the marketplace such as greater availability and access to medications (including opioids) in the home.

At the same time, packaging must meet growing expectations for product protection, quality, tamper-resistance, patient education, labeling, security and convenience in a variety of global environments.

Without a doubt, child-resistant packaging is a huge challenge requiring a mindset of prevention, collaboration and innovation. As more countries, including Japan, develop CRP regulations that protect curious children from harm, the packaging industry, government and distribution chains will need to embrace the value of change, developing proactive solutions and best practices that drive notable progress.

This paper addresses the dynamic world of child-resistant packaging, including the case for change, CRP criteria and testing protocols, regulatory and packaging trends, and material solutions.

The Case for Change

The U.S. Wake-Up Call

The concept for CRP originated in the United States (U.S.) after government officials reviewed a growing database of statistics about the cause of deaths in certain age groups. It was noted that in 1962, 450 children under the age of five had died as a result of poisoning. These deaths were from a variety of household substances, ranging from chemicals such as cleaners, detergents and bleach, to home and garden pesticides, to pharmaceuticals – both prescription and OTC.

Officials believed that changes in how potentially harmful substances were packaged could prevent future injury and death. As a result, the Poisons Prevention Packaging Act (PPPA) was passed by the U.S. Congress in 1970 and became effective in 1972. This act gives the Consumer Product Safety Commission (CPSC) – which is charged with protecting the public from unreasonable risks of injury or death associated with consumer products – the authority to issue requirements that certain household substances be sold only in child-resistant packages. It defined this as packages that are "difficult … for children under age five to open, but not difficult for normal adults to use properly."

The results speak for themselves *(see Figure 1)*. With the adoption of the PPPA, it is clear that more children are protected from fatal poisonings. Today in the U.S., deaths of children under five average less than 36 annually, or a decrease of more than 80 percent since 1972 when 216 children died.

Growing Concerns in Japan

Japan is experiencing a similar wake-up call. Typical drug distribution in Japan currently works like this *(also see Figure 2)*:

- Pharmacies receive pillow packs of drugs from manufacturers, which contain multiple blister packs, each containing either 10, 12 or 14 doses.
- When filling individual prescriptions, the pharmacist removes the required blister packs, tears off the required doses, and places the drugs with prescription information into a single plastic bag for the patient, which could include several prescriptions in one bag.

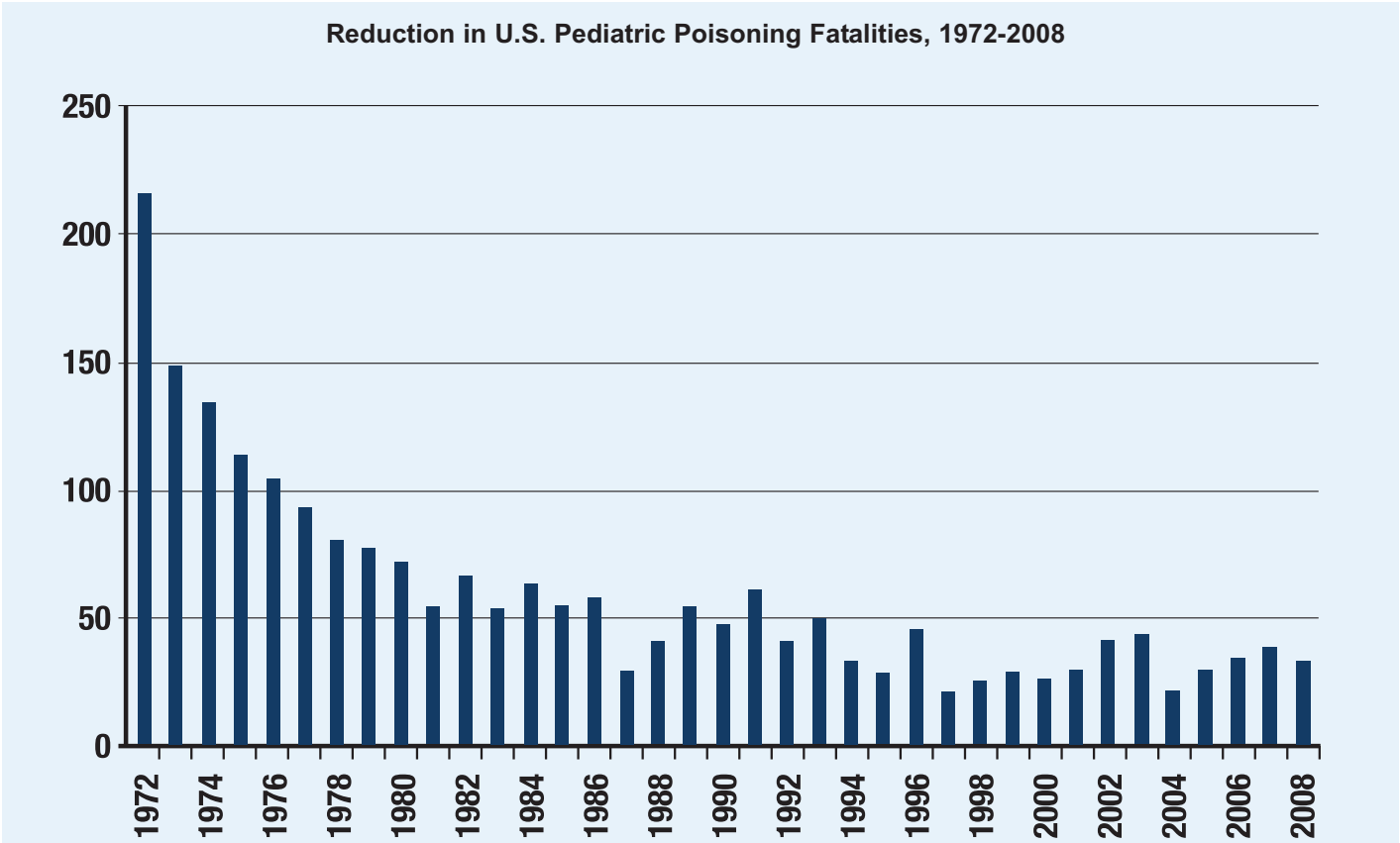


Figure 1

**Source: Consumer Product Safety Commission*

Typical Drug Distribution in Japan

Pharmacies receive pillow packs containing multiple blister packs of drugs with minimal push-through force.

Pharmacists tear off required doses, placing drugs with prescription information into a single plastic bag for customers, which could include several prescriptions in one bag.

Minimal push-through force makes it easy for children to extract multiple tablets.

Figure 2

The ability to push through the blister and extract the tablet easily is an important feature in Japan. However, having minimal push-through force works against child resistance, and in fact makes it much easier for a young child to extract multiple tablets from blister packs in a short period of time.

Data gathered by Japan's Ministry of Health, Labour, and Wellness (MHLW) on accidental ingestion of drugs and other substances by children suggest the need for regulation *(see Figure 3)*. In 2011, 21 percent of cases recorded were due to the ingestion of drug and quasi-drug substances, up from 13.8 percent in 2005.

A specific case study about two siblings in 2011 further illustrates the problem. A three-year old boy and two-year old girl accidentally swallowed 25 orally disintegrating tablets of a psychoactive drug and were transferred to a hospital in a semi-comatose condition. Not only could they easily access multiple doses, but orally disintegrating tablets are designed to have a sweeter taste and dissolve quickly in the mouth, making it easy for children to mistake the medication for fizzing candies such as the locally popular Ramune.

Health Hazard by Household in Japan

Statistics of Accidental Ingestion by Children				
	Tobacco	Drug & Quasi-drug	Other	Total Incidents –All Categories
2005	224 (30.9%)	100 (13.8%)	Toy 69 (9.5%)	725 (100%)
2006	231 (35.8%)	106 (16.4%)	Toy 55 (8.5%)	646 (100%)
2007	261 (33.6%)	137 (17.6%)	Toy 60 (7.7%)	777 (100%)
2008	159 (33.3%)	86 (18.0%)	Toy 37 (7.8%)	477 (100%)
2009	131 (31.2%)	72 (17.1%)	Metal 38 (9.0%)	420 (100%)
2010	130 (34.5%)	64 (17.0%)	Toy 34 (9.0%)	377 (100%)
2011	105 (30.2%)	73 (21.0%)	Plastics 32 (9.2%)	348 (100%)

Figure 3 **Source: Ministry of Health, Labour and Welfare*

Such data shows that Japan is indeed experiencing a growing problem with accidental ingestion of drugs that can lead to serious health hazards, and that solutions need to be considered – including CRP.

Consequently, on January 4, 2013, the MHLW notified The Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ), the Japan Self-Medication Industry (JSMI) and the Japan Packaging Institute (JPI) in an official letter (#0104-4) about its desire to enhance efforts to prevent accidental ingestion of medications and suggested the need for a child-resistant container. This was the first such MHLW recommendation and could result in formal policy development.

A Global Awakening

Facing similar poisoning statistics and case studies, a growing number of countries are putting CRP on their agendas. For example, the Indian Ministry of Health recently announced a national program to control chronic diseases in India, which will focus on many issues, including the prevention of child poisoning. In China, the Chinese Pharmaceutical Packaging Association (CPPA) issued a report urging CRP requirements and the government has indicated plans to institute such requirements in 2013.

As countries continue to awaken to the problem, it is expected that the pharmaceutical industry will see growing regulatory activity for CRP around the globe (see Regulatory Trends section of this article).

According to the latest data in a 2008 World Report[1] on Child Injury Prevention sponsored by the World Health Organization (WHO) and UNICEF, "CRP is one of the best-documented successes in preventing the unintentional poisoning of children. CRP has proved effective for medications, fuels, household chemicals and pesticides …and should be used on all drugs sold over-the-counter, to help prevent children from consuming these potentially lethal products. Countries should introduce laws mandating CRP for medications."

Child-Resistant Packaging Goals and Requirements

When the U.S. initiated regulatory efforts, it began by clearly defining the goals of CRP and establishing criteria in terms of what drugs required CRP.

This includes an important distinction with regard to child-proof packaging versus child-resistant packaging. According to the U.S. CPSC, "There is no such thing as child-proof packaging. So you should not think of packaging as your primary line of defense. Rather, you should think of packaging, even child-resistant packaging, as your last line of defense."

The intent, then, is to reduce the risk of child mortality by designing a package that is difficult for children under age five to open, but not difficult for normal adults to use properly. As the last line of defense, a child-resistant package should slow the child down enough to allow a parent or guardian to intervene before the child can ultimately access the contents and do harm.

In addition, while criteria have evolved over the years, the CPSC has identified which healthcare products must meet child-resistance requirements. These fall into four distinct categories:

- Prescription Drugs: Any drug that requires a doctor's prescription unless exempted from child-resistance requirements.
- OTC Products: Over-the-counter (OTC) drugs that contain specific amounts of aspirin, acetaminophen, iron, fluoride and several other listed substances. A full list can be reviewed on the Code of Federal Regulations website (see 16 CFR 1700.14).
- OTC Switched Products: Over-the-counter oral solid dosage products approved for OTC sales after January 29, 2002, that contain an active ingredient that had previously been available by prescription only. These are also known as OTC "switched" products. Examples include Allegra®, Prevacid® 24HR, Zyrtec®, Claritin® and Mucinex®.

- Clinical Trial Medications: Investigational products for clinical trials that are being dispensed on an out-patient basis, and that contain an amount of drug that could be expected to cause serious injury or illness to a small child.

A fifth category was added in November 2012. Any OTC or prescription product that contains the equivalent of 0.08 milligrams or more of an "imidazoline" in a single package will now require child-resistant packaging. Manufacturers of such products have until December 2014 to fully implement new packaging to comply with the ruling.

If the drug does not fall into these categories, CRP is not required for the drug to be sold in the U.S.

Child-Resistant Testing Protocols and Procedures

A protocol unique to U.S. regulation is a compliance requirement for an "F" rating related to the toxicity of the drug. This protocol entails determining the amount of a substance that would produce serious personal injury or illness in a 25-pound child.

If toxicity information is known and it is determined that only one dose can cause serious injury, an F=1 rating is assigned *(see Figure 4 for details)*. If toxicity information is not known, the packaging for that particular drug must meet the highest rating by default (F=1), meaning only one dosage can be extracted from the package or the test is considered a failure.

While the "F" rating protocol is unique to the U.S., other standardized testing procedures created in the U.S. are often leveraged by other countries. These procedures were an outcome of the PPPA to ensure that each package meets regulations for child-resistance and guarantees functional reliability. The CPSC amended this in 1995 to include a senior-friendly requirement and a recloseable package check. Today:

- Tests must be conducted in groups of 50 children in pairs, aged 42 to 51 months with a gender equivalence within 10%. If results are inconclusive, up to 200 children may be tested.
- Tests must also be conducted on 100 people ages 50-70 years, with 70 percent being women.
- For packages with recloseable features, after they are tested by seniors, they must be given to children to verify the retention of the child-resistance features.

For a package to be eligible for the market, it must be tested by accredited companies and pass two key tests: the sequential child test and the sequential senior test. These are summarized below (see 16 C.F.R1700.20(a)(2)(ii) in the U.S. or ISO 8317/EN 14375 in Europe for details.)

Sequential Child Test

The Sequential Child Test consists of two five-minute tests. In the first test, the children do not receive instruction and are given five minutes to open the package. Prior to the second five-minute test, they are visually shown how to open the package and told that they can also use their teeth, then given an additional five minutes to open the package. The pass-fail criteria is based on the percentage of children unable to open the package in each five-minute test segment and for the U.S., the criteria also consider the "F" rating.
For a package to pass the child-resistance protocol:

- First test segment: More than 85 percent of the children must not be able to open the package within the first five minutes – or fewer than eight children are able to open and access the number of doses that can cause serious injury or illness (per the "F" rating).
- Second test segment: Given the children were shown how to open the package in the second test segment, an effectiveness of more than 80 percent of children must be achieved.

Again, in the U.S., a test failure is any child who opens or gains access to the number of doses that could pose serious personal injury or illness per the"F" rating, or in

Health Hazard by Household in Japan

Toxicity and the "F" Rating

- **The toxicity of a drug product must be determined, and if requested, submission of the toxicological data must be based on the CPSC's Office of Compliance.**
- **The determination of the amount of a substance that may produce a serious personal injury or serious illness shall be based on a 25-pound child.**
- **When this information is not known, it is recommended that the packaging meet the highest rating by default.**

The Scale

- **F=1. One dose can cause serious personal injury or illness**
- **F=5. Five doses can cause serious personal injury or illness**
- **F>8. Greater than eight units can be ingested before serious personal injury or illness occurs. However, the protocol still allows access of up to eight units during testing, or the test is considered a failure.**

Figure 4

the case of F>8, a child opens or gains access to more than eight individual units in 10 minutes of testing.

Sequential Senior Test

Testing children is only half of the process, as the package must also pass the Sequential Senior Test. This test has two timed segments: one five-minute test to open the package, followed by another one-minute test to open the package and prove senior-friendliness. For a package to pass this test, more than 90 percent of the participants must open the package in each segment. If the package is opened within the first 30 seconds in the second segment, it is considered a "good, senior-friendly" package.

Global Regulatory Trends

As mentioned, countries worldwide are slowly awakening to the growing problem of accidental pharmaceutical poisoning. It is proven that medicinal drugs, especially analgesics (pain medications), are the leading cause of non-fatal poisoning in children in middle-income and high-income countries. For example:

- United Arab Emirates: 55 percent of poisonings are due to analgesics, non-steroidal anti-inflammatory drugs and antihistamines in children ages one to five (per a 1997 report).
- Turkey: 57.7 percent of reported poisonings are due to accidental ingestion of drugs, most frequently of analgesics in children ages one to five (per a 2004 report).
- U.S.: Despite a dramatic reduction in fatalities since 1972, 50,000 pharmaceutical exposures were reported in 2003 in children under age five, with prescription drugs implicated most often.
- In England and Wales, 12.8 percent of unintentional poisoning deaths in children under age 10 were due to medications (from 1968-2000).

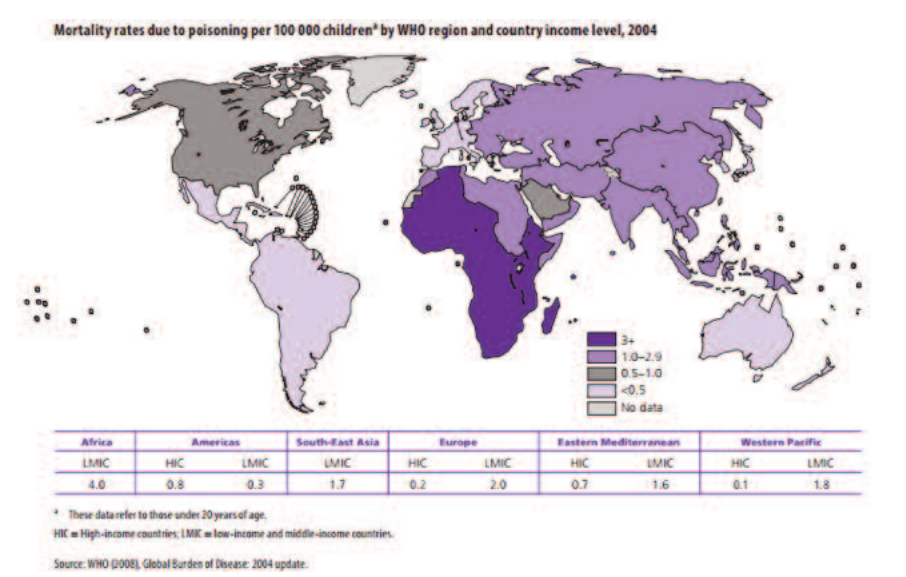
Despite such statistics, and despite data clearly showing that CRP can save lives, only a handful of high-income countries have regulations in place, such as the U.S., the United Kingdom, Australia, Canada, New Zealand and the European Union (EU).

The Impact of Income

According to the WHO report referenced earlier, acute poisoning from harmful household chemicals and pharmaceuticals accounted for an estimated 45,000 deaths annually in children and young people under age 20. Generally, infants under one year of age suffer the highest mortality rates, followed by children under age five. The global mortality rate for this age group is 1.8 per 100,000. For high-income countries, the rate is 0.5 per 100,000 while for low-income and middle-income countries, it is four times higher at 2.0 per 100,000.

This is not surprising since low-income and middle-income countries typically cannot afford as much regulatory protection. Africa, in fact, has the highest mortality rate of 4.0 per 100,000 children *(see Figure 5; darker colors represent higher mortality)*. Conversely, regions with higher incomes and/or CRP regulations tend to have lower mortality rates.

Child Mortality Rates from Poisoning Higher in Low-Income Regions[1]



Africa	Americas		South-East Asia	Europe		Eastern Mediterranean		Western Pacific	
LMIC	HIC	LMIC	LMIC	HIC	LMIC	HIC	LMIC	HIC	LMIC
4.0	0.8	0.3	1.7	0.2	2.0	0.7	1.6	0.1	1.8

* These data refer to those under 20 years of age.
HIC = High-income countries; LMIC = low-income and middle-income countries.
Source: WHO (2008), Global Burden of Disease: 2004 update.

Figure 5

[1]Most recent WHO mortality data available

One exception can be found within the Americas. While mortality rates are lower overall compared to other regions, it's interesting to note that the higher income countries within the Americas have a slightly higher mortality rate than their low- and middle-income Americas

counterparts. This is likely due to three contributing factors:

- More disposable income for pharmaceuticals and household products can increase the opportunities for poisoning.
- The growing use of prescription drugs by adults and children, from pain relievers and heart medications to sedatives such as sleep aids, increase the availability of these drugs to young children.
- The increase in sustained-release medications can contribute to more severe poisonings.

The European Union Approach

European directives 1999/45/EC and 1967/548/ECC lay out provisions regarding the classification, packaging, and labeling of drugs and other potentially dangerous substances, but there aren't any regulations in place that require child-resistant packaging. When CRP is utilized, however, the guidelines are very similar to those in the U.S. with a few key distinctions:

- CRP is not absolutely required by each EU member state. Instead, the individual EU members have the right to determine product requirements for their country and put laws into place that enforce the regulations. For example, Italy chooses to participate with the regulations and has very strict product requirements, but Ireland is significantly more lenient and requires very few drugs to be packed in a child-resistant package, while France has no CRP requirements.
- For the Sequential Child Test, children are NOT instructed to use their teeth in the second five-minute test.
- EU standards do not use the "F" rating for toxicity and hazard. During testing, children may access up to eight doses during the testing, regardless of the level of toxicity. As long as the package maintains the 85% and 80% effectiveness score in the two timed testing segments respectively, it is deemed child resistant.

Evolving U.S. Regulations

Meanwhile, changes to existing regulations are under discussion in currently regulated countries, including the U.S. As mentioned, despite overall child poisoning deaths being cut in half, deaths specifically due to medication ingestion have actually doubled since the 1970s, from 36% to 64% according to Safe Kids Worldwide. While this alarming statistic is partly due to the increasing presence of drugs in the home, it also points to the need for improved CRP solutions. Clearly, the U.S. has been more successful at packaging household chemicals in child-resistant containers than pharmaceuticals.

One potential solution for the U.S. is to shift away from the popular child-resistant capped bottle to more innovative blister pack solutions that reduce access to large doses. Currently, if a child opens the bottle, they gain access to all of the tablets in the bottle, increasing the likelihood for serious injury, illness or death. Large pharmacies such as Wal-Mart are already introducing alternatives.

Packaging Trends

As Japan contemplates CRP regulation, a shift in the packaging paradigm for pharmaceuticals may need to occur. A variety of CRP options are available that already meet U.S. and EU regulations. Designing the ideal CRP solution should include the following elements, which reflect best practices based on decades of industry experience and understanding of both patient and manufacturer needs:

- Balance an effective CRP solution with senior-friendly ease of opening.
- Encourage the engagement of the CRP feature when product is not in use.
- Improve the customer/patient experience with the product rather than degrading it.
  - Utilize ergonomics.
  - Add features to improve the patient experience.
- Ensure minimal impact of the cost of goods sold.
- Provide the opportunity to rebrand the product with exclusive designs that help capture market share.
- Improve the sustainability of the package, reducing waste.

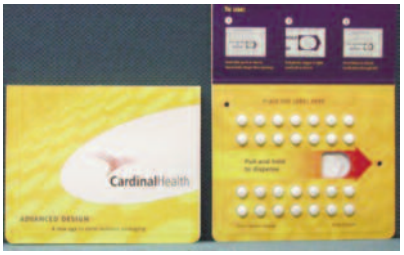
These elements of design can be leveraged and modified as necessary for the Japanese consumer. Below are examples of child-resistant packages used in the regulated regions of the world, including a few more innovative designs recently brought to market.

Bottle with Child-Resistant Cap

The most popular child-resistant package for prescription drugs in the U.S. is the amber bottle with a child-resistant cap closure

even though once opened, a child can access all of the contents. In the pharmacy, all oral solid drugs are counted and dispensed into this type of bottle, unless the direct-from-manufacturer package is a blister package. This was the original solution developed when the PPPA went into effect, and can be mass manufactured. While inexpensive, it may eventually be replaced by the blister pack to prevent access to all the pills. Note that a similar package is often used for OTC and OTC-switched drugs. It is an opaque bottle (typically white) with a child-resistant cap and is typically used when the drug is sold in quantities of 30 or more.

Recloseable Blister Slide-Pack



This package is an example of one of the earlier designs for a recloseable, semi-rigid blister slide-pack solution designed by Cardinal Health. The package relies on the user being able to read and follow the instructions to release the tablet from the package – something that children in the Sequential Child Test simply are not able to do. Consequently, this package has an F=1 rating. The back of the card is a paper and foil combination with a clear plastic shield between the foil and the paper. After removing a perforated cut-out, the user can slide the plastic shield to the right, aligning the holes with the foil back of the tablet, which can then be pushed out of the card. Despite instructions, it may be complex for some seniors and there are some limitations on pill size.

Shell Design with Push-Button Technology

This package is an example of one of the earlier designs for a recloseable, semi-rigid blister slide-pack solution designed by Cardinal Health. The package relies on the user being able to read and follow the instructions to release the tablet from the package – something that children in the Sequential Child Test simply are not able to do. Consequently, this package has an F=1 rating. The back of the card is a paper and foil combination with a clear plastic shield between the foil and the paper. After removing a perforated cut-out, the user can slide the plastic

Standard Blister with Child-Resistant Lidstock

A potentially simpler child-resistant solution is the standard blister configuration with a child-resistant lidstock, which is one of the most common solutions for OTC medications. A variety of manufacturers make a child-resistant lidstock, including the Guardlid® from Amcor Flexibles, which is often used in the U.S. and Europe. It is a less expensive manufacturing solution with high flexibility in design and materials. Typically, the construction has a peelable paper that makes it difficult for children to open. While this solution passes both the child-resistant and senior-friendly test protocols, in the U.S. it tends to receive senior complaints as difficult to open versus other more innovative solutions.

Sliding Child-Resistant Blister Pack

The Burgopak® is an award-winning sliding child-resistant blister package, receiving the "Most Innovative Child-Resistant Packaging Design" at the PharmaPack Paris show in February 2012. Unique features include the integration of a patient information leaflet and sliding blister pack with the outer box, ensuring that the product and leaflet are never separated from the package. This package can only be opened by applying pressure at two separate points– making it easy for a senior to open, but too complex for a toddler. This package is available in a variety of configurations and has the F=1 child-resistant rating. Special manufacturing equipment may be required, however, and costs may be higher.

Recloseable Child-Resistant Carton/Blister Pack

Stora Enso's "Pharma SHR (Small Hands Resistant)" package is a recloseable child-resistant carton/blister package. Because the blisters are never separated from the carton, it is ideal for dispensing highly toxic drugs requiring a high level of child safety and ease of senior use. This package

supports complex dosing regimens, is popular for clinical trial drug dispensing and can incorporate compliance-enhancing features. It can also be used for prescription drug dispensing direct from the manufacturer. It supports thermoforming materials or Cold Form Foil, although special equipment may be required.

Child-Resistant Folding Box with Sliding Blister Card

The Keystone Ecoslide-RX® package has also been adopted by Wal-Mart Pharmacy for generic drug dispensing. The carton and blister are integrated and can't be separated. Unlocking the contents requires a thumb press on a lock-release button, a process that delivers excellent child resistance while resonating well with senior users. Compliance-enhancing features are also included with this package, ensuring multi-purpose utility. It is made with 100 percent recyclable material, helping companies fulfill their sustainability objectives. Furthermore, the package can be integrated into high-speed blistering lines. There may be some limits in pill sizes.

Smaller, Efficient Child-Resistant Blister

A more recent entrant to the market is MWV's Shellpak® Renew package, which is designed to achieve the highest level of child resistance and senior friendliness while retaining an F=1 rating. It provides the same number and size of pills in a smaller package size, minimizing waste while also using recyclable materials. The easy-press button utilizes Optilock technology to simplify package opening, and the overall design improves pill expression, pharmacy accuracy and efficiency. It is available in multiple configurations, but cannot be used with Cold Form Foil. Published data finds a statistically significant improvement in patient adherence versus bottles.

Tailoring Solutions to Specific Needs

Clearly, there are already many solutions available in today's market that are child resistant and senior friendly. Instead of investing in new package designs, companies can choose or modify an existing option that best meets their drug distribution goals and cost-performance needs. Note that if the current drug distribution process in Japan does not change, the only drop-in solution is the use of the child-resistant lidstock. However, this type of lidstock removes the ability to easily push the tablet through the back of the blister, making it more difficult to open.

Materials to Support Packaging Trends

As countries like Japan evaluate the need for CRP regulation, they are in a unique position to select from a variety of proven practices and package designs. It appears that recloseable thermoformed packages are growing in popularity as the easiest way to bring a drug to market that protects children while being senior-friendly.

Meanwhile, it's important to note that drug formulations are becoming increasingly complex and moisture sensitive, requiring higher barrier materials in the blister package to adequately protect the drug. Although Cold Form Foil can meet the moisture barrier requirements of a drug formulation, it may compromise other benefits of thermoformed packages, such as:

- Smaller pack size
- Patient portability; ease of use
- Flexibility in package design

Given the requirements of today's child-resistant packages, it is quite common to see ultra-high thermoformable materials (such as Honeywell Aclar® films) used as the material of choice. These help meet requirements for the latest generation hydroscopic pharmaceuticals and drug delivery technologies, increasingly sensitive drugs, global requirements (from Zones I-IV), child resistance, senior friendliness, compliance-enhancing features and design flexibility.

Trends in blister packaging also include the need for higher stability, such as a high moisture barrier, to extend shelf life across the complexity of pharma-outbound supply chains and global climates (e.g. hot, cold, dry and humid).

As shown in *Figure 6*, low moisture barrier films such as polyvinyl chloride (PVC) and polyethylene

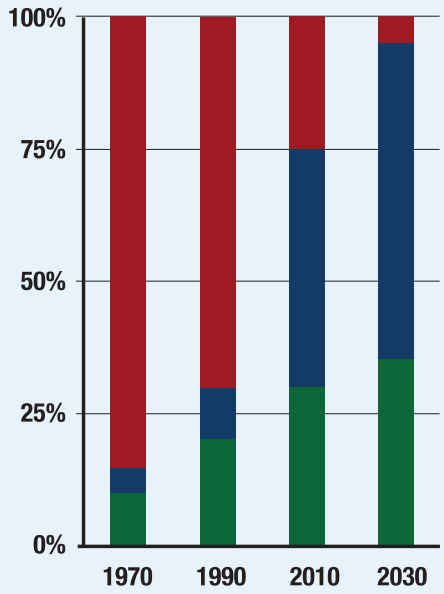
terephthalate (PET) are being phased out by mid-range moisture barrier films such as polypropylene (PP), cyclo olefin copolymer (COC), 30-90g polyvinylidene chloride (PVDC) and 15-23 micron Aclar® films because of the increasing sensitivity of drug formulations. Also growing in popularity are high- and ultra-moisture barrier films such as 120g and higher-PVdC, 51-152 micron Aclar® films and Cold Form Foil (CFF).

Material Adoption Trend for Moisture Barrier[1]

Low Moisture Barrier Films
- PVC
- PET

Mid-Range Moisture Barrier Films
- PP
- COC
- 30-90g PVdC
- 15-23 µm Aclar® Films

High to Ultra High Moisture Barrier Films
- 120g and higher-PVdC
- PET



[1]Based on research from www.pharmacircle.com (2010) and Pharmaceutical Technology On-Line, Current Status of Drug Delivery Technologies and Future Directions – Rajan K. Verma and Sanjay Garg, February 2001

Figure 6

Conclusions: Proactive Packaging

The case for change is clear. While childhood poisonings due to accidental ingestion of harmful household substances is on the decline, poisonings specifically due to pharmaceuticals are on the rise worldwide – and so are related discussions about CRP regulations and solutions.

The prospect of both new and changing regulations presents its own set of challenges. However, it also provides pharmaceutical packaging companies with the opportunity to collaborate with government institutions and industry colleagues, and to proactively develop innovative solutions and best practices for CRP. The overriding goal should be to prevent and minimize pharmaceutical poisonings and reverse the trend.

As members of the pharmaceutical industry, we need to question current packaging approaches from a child-resistance and senior-friendly standpoint, and investigate viable, long-term alternatives. This includes leveraging protocols, procedures and designs that work, and dedicating ourselves to improving and replacing those that don't.

Change is never easy, especially in countries like Japan with a firmly entrenched distribution system. If change, however, can make a difference in saving the lives of young children and preventing harm, the return on investment is well worth the effort – many times over.

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Ms. Melissa B. Green is global strategic marketing manager for Honeywell's Healthcare and Packaging business, and is responsible for developing strategies to promote Aclar® films globally to pharmaceutical companies. Green, who is a Six Sigma Black Belt, has held various roles within Honeywell, including product manager for Aclar Films and market development manager for Aclar in North America. She holds a bachelor's degree in Mechanical Engineering from Bucknell University and a master's in business from Lebanon Valley College, and is a board member of the Healthcare Compliance Packaging Council (HCPC).

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