



# ‘Cold Chain’ Packaging for Health: New Products and Coming Visions

By Sanford L Cook

In normal everyday shipping methods, ambient temperatures can swing to extremes, as airplanes sitting on the tarmac heat up on hot summer days, and then flying at altitude where temperatures drop below freezing. These temperature swings can be harmful to pharmaceutical products of all kinds, so there are many ways packagers and shippers use to moderate the temperature. There are also ways to test how effective packaging is at keeping internal and product temperatures within tolerances.

In the last 10 to 15 years there has been a proliferation of companies that manufacture containers and devices that protect temperature-sensitive products. The transport of biopharmaceutical goods is regulated by the FDA, and the government requires data to validate<sup>1</sup> that shipping methods and storage materials are adequate to maintain safe interior environments. The methods and tools that the pharmaceutical industry has been using for this protection and validation are now making their way into consumer goods protection and monitoring.

### Moderating temperature

Available shipping technologies include expanded polystyrene, urethane, advanced plastic foams, captured-air-in-bags, vacuum panels, and even refrigerated freight containers. Phase-change materials (PCMs) beyond merely a water/ice substitute are now used as an interior temperature stabilizer, changing phase to absorb temperature extremes. With PCMs and the proper design or coordination of insulation, packaging can now control internal temperatures within a narrow range for up to five days as the external temperatures swing from -22° F (-30° C) to as high as 104° F (40° C).



Thermochromic inks can be a reassuring indicator that sensitive products haven't been exposed to harmful temperatures.

Today's pharmaceutical packagers mix and match existing product technologies to best regulate temperatures for each application. Education about these products and the knowledge to skillfully use them efficiently has



The pharmaceutical industry relies on accurate, reliable temperature recorders that might be equally valuable to consumer goods and food product manufacturers.

also morphed into an essential industry of its own (best taught by independent packaging specialists/consultants<sup>2</sup>, such as those at [www.packagingconsultants.org](http://www.packagingconsultants.org)). Being the lowest cost producer providing the lowest prices at the highest quality and delivery, plus creative marketing and service programs, has become the formula for success in the maturing packaging supplier industry.

Also developing at a rapid rate has been the accurate low cost monitoring of temperatures to provide assurance that products have not been exposed to unsafe conditions. As technology in these areas matures, the result will be new devices that can merge all of this knowledge into low cost, easy-to-use products. As the costs come down, more consumer goods companies will see the benefit of carefully monitoring their products during shipment.

For example, electronic temperature data loggers have been on the market for at least 15 years. The newer ones are very small—the size of a quarter or a credit card—and can record extremely accurate information. These devices will keep track of the information for various durations and will encrypt the data to conform to FDA's regulatory requirements. The newest data logging units are capable of transmitting temperature data remotely at any point during shipping or downloading directly to a computer after shipping.

### Validation by the end-user

However, there are still many challenges in the protection of sensitive products. Product diversion, hijacking, and counterfeiting are continuing issues that have been highlighted in major media recently, pressing the industry to keep track of the distribution and storage of goods and inventory more thoroughly. RFID offers some promise to monitor shipments at various points in the distribution channels; however, investigation has shown that product diversion can still take place between the manufacturer's shipping dock and receipt at the consumer. Each time the package is handled during the often complex distribution process, an opportunity is present to divert the product.

Since there is no way to protect a shipment at every point in the distribution channel, true validation must come when the product reaches the end user. The only way to ensure that the product used by the final consumer (hospital, pharmacy, or patient) is authentic is to have that consumer validate the authenticity through a separate validation system that connects the end-user back to the manufacturer. Inexpensive photo or electronic readers will allow consumers to read a special label and compare that information to manufacturer's "gate-keeper."

This reader will be able to confirm authenticity or identify an anomaly and warn the consumer not to use the product. The coded information may be a digital type label that may overlay date, batch codes, and other time-revolving data—or a completely unique code—that would be nearly impossible for anyone out of the system to track.

### Confirming food quality

For pharmaceutical as well as food applications, there is one more immediate method to detect and visually indicate a temperature infraction that may come into more prevalent use. Temperature-sensitive inks on labels or on primary packaging surfaces can provide a visual confirmation that the product integrity has not been compromised.

These inks change color, appear, or disappear when triggered by temperatures that would harm the product. Once nonreversible inks change color from out of toler-



**The future of consumer protection seems to be an end-user verification system where the product in hand can be verified through a robust database.**

ance exposures, they indicate that the product inside might not be safe to consume. Handlers at the grocery store or consumers at home will know if that food has been compromised by temperature. These specialty inks may be printed directly on the product's primary packaging for food and medical products or hidden in one bar of a standard bar code.

Actual packaging material technology will continue to move forward toward better and cheaper ways to protect product, but the recent technological breakthroughs have been in the monitoring of temperature, identification, and tracking goods and inventory with the use of digital and electronic product codes. If manufacturers and industry organizations combine all these methods of information collection to support the salient characteristics of each system and supplement each technology's weaknesses, more levels of validation will allow for more consumer protection.

For example, data loggers can transmit information relating to temperature strategically located in the interior of any package. This information could be collected remotely and automatically in linking software during distribution and storage, and added to the manufacturer's data and distribution data. If all of that data is centrally located for confirmation, then all that remains is a way to tap into that data. Eventually, hospitals, pharmacies, patients, food handlers, and everyday consumers will be able to confirm they have valid products inexpensively by tapping into that data with reading devices connected to the database. ■

<sup>1</sup> If validated certification for packaging is required, it is highly recommended to use the services of impartial independent test laboratories.

<sup>2</sup> Independent consultants that are not directly employed by or obliged to suppliers by incentives may be conferred with to derive objective information and advice.

*Sanford L. Cook, CPP, is president of Thermal Packaging Solutions, a consulting and product development resource to the biopharmaceutical and food packaging industries. Cook has been the chief executive officer, chief engineer, and chief marketing executive for global companies engaged in the design, documentation, validation, testing, and manufacturing of tools and processes that protect sensitive products in transit.*