

# Quality, then Cost

*The economy is straining packaging budgets, but packaging engineers report that maintaining quality is still more important than cost cutting.*

By Daphne Allen  
Editor



**E**conomic ups and downs are certainly driving change in the pharmaceutical and medical device packaging markets, perhaps accelerating trends that began long ago, such as downgauging and lightweighting. But given the heavily regulated industry and its conservative, quality-minded packaging professionals, change happens slowly. While such a pace often means that innovations take time to penetrate the industry, it also means that attempts to reduce operating costs typically do not happen quickly.

In fact, drug and medical device packagers still put quality concerns ahead of economic, and for good reason, given the critical nature of their products. According to the results of a buying survey *Pharmaceutical & Medical Packaging News* conducted through Readex Research, quality edges out cost. Asked to rank the importance of certain characteristics when selecting a vendor/supplier on a scale from 1 to 5 with 5 representing "very important," respondents ranked quality first at 4.7, with price ranked at 4.3.

Of course, given economic pressures, packaging professionals are looking for ways to boost or streamline productivity and consolidate expenses where they can. According to our annual salary survey, several respondents indicated significant involvement in automation

and outsourcing, centralization, lean manufacturing, offshore component sourcing, and downsizing programs. (For more details on our annual salary survey, please see page 14.)

But if any packaging professionals have been tempted to skimp on quality, a number of very high-profile recalls and plant shutdowns in 2009–2010 may have given them just pause. After one of the most trusted drug manufacturers recalled millions of containers under long-respected brands owing to consumer complaints and negative inspection reports by FDA, the rest of the industry most likely took a second look at their own facilities and procedures to stave off any potential quality issues.

Despite cost cutting, the supplier base supporting pharmaceutical and medical device packagers continues to report high demand for materials with demonstrated product safety. "Without a doubt, drug safety and efficacy are the primary drivers of pharmaceutical packaging," notes Georgia Mohr, pharma segment director for Perfecseal. "Therefore, packaging technology is driven by a long list of drug safety and efficacy issues, which includes but is not limited to maintaining sterility and efficacy throughout shelf life, increasing drug compliance, and eliminating administration of the wrong drugs."

There is hope that innovation exploration could pick up, as the drug indus-

try is developing more convenient dosing means. "Pharmaceutical companies are introducing many ways of delivering drugs into the body more effectively including oral, inhalation, transdermal, injections, nasal, etc. In addition to drug safety and efficacy, the method of drug delivery dictates the packaging requirements to a great extent," says Mohr.

Packagers may also be called upon to help address healthcare challenges such as medication errors and nonadherence with drug regimens. For instance, FDA held a public workshop on developing guidance on naming, labeling, and packaging practices to minimize medication errors. Non-adherence with drug regimens was also discussed, with one presenter calling it "the most common type of medication error studied in ambulatory self-care settings."

The challenge for drug and medical device packagers will be finding ways to maintain (or step up) quality and to foster innovation in a not-so-rosy economy. Material and equipment providers are feeling the strain as the industry pushes them to provide more for less, but nimble suppliers are devising creative solutions.

### INCREASED SCRUTINY

In May, Joshua Sharfstein, FDA's principal deputy commissioner, outlined FDA's quality expectations before

the U.S. House of Representatives Committee on Oversight and Government Reform. Sharfstein was present to discuss FDA's oversight of McNeil Consumer Healthcare LLC, which over the past year has recalled millions of OTC drug products. "The cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations are intended to ensure purity, potency, and quality of drug products, and to prevent unsafe products from reaching consumers," he testified. "A violation of cGMP does not necessarily mean that a product is hazardous to the public. It does indicate, however, a breakdown in a manufacturer's quality system and is an indication that a company needs to take effective steps to fix the problem promptly." Sharfstein said that FDA is working with Congress to rework its approach to enforcing quality.

Jean-Francois Leclair, director of marketing, Amcor Glass Tubing Americas, believes "FDA regulations and expectations are becoming more stringent to reflect the desire for flawless medical treatments." In that context, he says, "we already see a very strong trend of increasing quality expectations and documented and controlled processes."

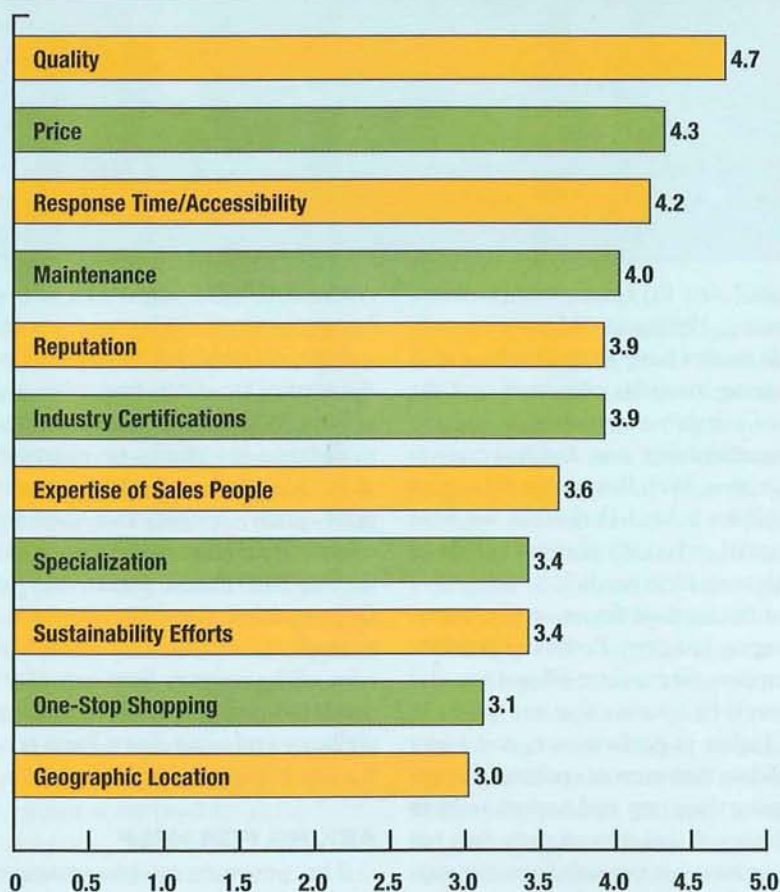
Could FDA toughen up when it comes to ensuring drug and medical quality? When it comes to maintaining drug product temperatures, some suppliers are already sensing greater scrutiny. "There is increasing demand to be able to ship and store products that need to be kept at 20°C–25°C or 15°C–30°C," says William Hingle, director of marketing, Cryopak. "This is being driven not only by new product development but also through increased regulatory scrutiny of such products. Many times the value of these products is significantly less than that of other temperature-controlled products, therefore the added packaging required to maintain these products adds stress into the supply chain. Suppliers such as Cryopak are developing cost-effective products to meet this challenge."

Manufacturers are asking more detailed questions of suppliers, reports Tom Misik of Belco Packaging Systems Inc. "There is an ongoing effort by manufacturers to assemble vendor documentation from even nondevice product suppliers, such as the heat sealing equipment we provide. Companies have always asked us for performance data on critical equipment processes, but the requirement to inspect internal documents is relatively new. They are drilling down and looking into vendor systems. These companies are developing approved supplier procedures and need such documentation to satisfy their internal auditors. In this business, you have to demonstrate high confidence and competence. We welcome those inquiries."

Material converters have seen changes in customer requests demonstrating a renewed focus on improving quality. "We see an increased amount of requests for documentation, LOAs, etc. even from long-term customers," says Angela Roggenhofer, sales and marketing manager for Tekni-Plex. "Either induced by direct FDA requests or audits or rather as a preventive measure stirred up by issues at another company, many pharmaceutical companies are revisiting their procedures and have begun addressing issues that might have been slumbering for years, to catch them before FDA does."

Suppliers are stepping in to satisfy "unmet needs for high-barrier, primary packaging for a variety of drug-delivery

#### Importance of Characteristics When Selecting a Vendor/Supplier



Results from a 2010 subscriber survey by Readex Research for *Pharmaceutical & Medical Packaging News*. Respondents were asked to rank the above-listed characteristics when selecting a vendor. A score of 1 represents "not at all important," while a 5 represents "very important."



formats," says Ed Haedt, vice president, marketing, Perfecseal. "Many customers in this market have shared with us their packaging materials objectives and the lack of suitable alternatives to support their sustainability, cost, and end customer objectives. With Bemis material science capabilities behind Perfecseal, we have substantial technical collateral to help us quickly meet these needs."

For the medical device, sterile barrier packaging industry, Perfecseal is focusing on new thermoform-fill-seal top and bottom web systems that are lower in cost, higher in performance, and easier to validate than current options. "We are designing these top and bottom webs to be turnkey so that the company does not need to source a top web from one supplier and a bottom web from another. With this mated web approach, we can take total cost out of the system."

Adds Justin Schroeder, director, marketing and business development,

Anderson Packaging: "The past year has certainly opened some eyes in the industry on how cost cutting and losing the quality focus can negatively impact a firm. Whether [a manufacturer is] packaging internally or outsourcing work to a partner, a mishap caused by poor quality systems can have severe effects. It reinforces the notion that a firm needs to choose partners very carefully, and not simply on low cost. We have always strived to be on the leading edge of the industry from a quality and regulatory perspective. It certainly takes vigilance and a top-down focus on continuous improvement."

### ASKING FOR HELP

The pressure on pharmaceutical and medical device packagers may be unprecedented. "There is no doubt in our minds that the industry is transforming," says Leclair. "As the pharmaceutical companies are building

their R&D strategies for the future, in many cases through M&A, there is constant striving for production efficiency. It has become a necessity to evaluate and understand real costs and identify where value resides within everyone's operations. For instance, we have seen several large pharmaceutical companies proceed with global tenders and eBids to enhance and rationalize their vendor base. With very large pieces of business at stake, these tenders have forced us to clearly define our offering and to make sure that we can position a sustainable and sound value proposition. This means revisiting our operations to identify potential cost savings, but also refining our products and service to improve the offering."

In order to maintain expected quality levels while under economic strain, pharmaceutical and medical device manufacturers are asking their packaging suppliers for assistance. "The economy has driven more customers to become more lean," says Tim Saarinen, commercial director of Amcor Flexibles Specialty Performance. "Demand for cost-effective solutions by all customers coupled with more demand for generic products have continued to drive Amcor's continuous improvement (CI) processes. Amcor continues to have both internal and external CI projects with customers and suppliers to improve overall efficiency and supply-chain excellence. Our production sites continue to strive for improvements in all areas of quality with a 'zero defects' mentality utilizing poke yoke and other CI methodologies, stringent change control processes to maintain product integrity, and insisting on the highest standards in the quality systems."

Supplier investments in new facilities and machinery often result in improved efficiencies that could benefit manufacturers. "We have just finished a six-year retooling and modernization project in which we invested significant capital in the latest equipment throughout manufacturing," says Ward Smith, director of marketing for Keystone Folding Box Co. "Our goal is to produce the highest-

quality packaging at the fastest rates, and our investments will help us achieve manufacturing efficiencies. If a supplier doesn't reinvest and modernize, it becomes a weak link in the supply chain."

Purchasing machinery, however, may be a bit tougher for packagers when capital budgets are tight. "In tough economical times when our customers are closing sites and laying off people, the investments in equipment are scarce and have to go through an intense approval process," says Dirk Corsten, managing director, Uhlmann Packaging Systems LP.

Even contract packaging firms may be rethinking new equipment purchases. Richard Bahr, president of MGS Machine Corp., a provider of advanced secondary packaging systems, says that a few of the contract packagers he works with have gotten short-term contracts with their own drug company customers ranging from three to six months, and that simply may not be enough time to acquire new equipment. "They may not be able to buy and install capital equipment in that short of a time, and the payback time may not even be enough to justify the investment. The contractors may then just retool or rebuild existing equipment, or rely more on manual labor to complete the project."

Corsten says that Uhlmann has worked closely with some of its customers "to find ways to maintain and upgrade their current equipment base, instead of purchasing new machines altogether. For example, in an attempt to utilize older Uhlmann blister machines, we've initiated our OEM-rebuild program. In this program, many machines have been upgraded and rebuilt to cope with the latest standards and requirements. Every machine is backed up by a full OEM warranty. The companies that went through this program realized a significant saving in the overall investment, and the equipment is as good as new."

For new equipment purchases, Bahr says that drug companies more and more are asking vendors to participate in bidding processes. Part of that work

often entails having machinery builders prepare potential floor plans and complete other engineering tasks, even before a contract is signed. "These companies often have reduced engineering staffs, so we are taking on more of that work."

Such upfront effort can put machinery suppliers in an awkward position. To secure a contract or win a bid, these suppliers want to present their best solutions at the outset. But if such work is done before a contract is signed, there is the chance that the solution presented by one machinery provider could be shared and implemented with another. Time is also a factor. "If brought in early, we can

tical packaging materials in different locations and on different continents. Tekni-Plex has already addressed this need with film converting plants in the United States, Argentina, and Belgium and is further expanding to offer manufacturing capabilities in Asia."

Material converters have been diversifying in recent years, becoming more of solutions providers than strictly materials suppliers, while material suppliers have been getting out of the solutions business, says Peter Schmitt, managing director of Montesino Associates. He says converters have evolved into "material-neutral suppliers focused most on providing a solution rather than a single material."

*"If a supplier doesn't reinvest and modernize, it becomes a weak link in the supply chain," says Ward Smith of Keystone Folding Box Co.*

help solve an engineering problem, but we take a risk that ideas could be taken elsewhere," says Bahr. "But if we are drawn in at the 11th hour, it may be difficult to make stuff happen fast."

When it comes to materials and containers, manufacturers are also asking vendors to guarantee supply continuity and consistency. "Oversight from FDA is increasing," says Teri Meadow of Oliver-Tolas Healthcare Packaging. "Many of our customers are making investments in high-quality materials and reliable suppliers/partners to minimize the risk and cost and enhance patient health. At Oliver-Tolas, our quality mission and process extend beyond our company to our suppliers. We are partnering with suppliers who understand the quality requirements of the medical and pharmaceutical industries. We have also invested in unique capabilities, such as vision systems, as added assurance of our product quality."

In addition, "more than ever before, customers are also looking at redundancy in production," says Roggenhofer from Tekni-Plex. "The globalization trend is definitely here to stay, and with that, so is the need for suppliers that offer facilities that can make iden-

Schmitt points to Rio Tinto's sale of certain Alcan Packaging businesses to Amcor and Bemis, shifting its portfolio back to raw material mining and processing, and to the planned acquisition by Constantia Hueck of converter Tobepal.

Klöckner Pentaplast continues to diversify its material offerings, and the firm positions itself as an "enabler for pharmaceutical and medical device manufacturers presenting a product to the market," says Daniel Stagnaro, business manager of pharmaceutical films for the Americas. "With our modeling software BlisterPro, Klöckner Pentaplast offers material selection and blister and tooling design assistance."

Working with a supplier that can provide multiple solutions along with supply-chain management could shorten a schedule and even reduce a manufacturer's output of working capital, says Aileen Ruff, group product manager, commercial packaging, for Catalent Pharma Solutions. "Companies can then refocus their energy on other projects. We find that our customers are being more strategic, thinking less about procurement, and more about supply-chain solutions. With expertise across the global Catalent network, we

can offer integrated supply chain solutions that provide such cycle time and working capital benefits, while reducing the risk and complexity that results from relying on multiple suppliers.”

### A CHANGING INDUSTRY

As competition intensifies among pharmaceutical and medical device manufacturers, companies are responding not with new blockbusters, but often with line extensions tailored to special needs and markets. Such a shift means that manufacturers are frequently producing shorter runs and therefore need flexible equipment. “In September 2009, we launched the latest model of our ultra flexible and fast changeover blister machine and cartoner, the Blister Express Center 300 (BEC-300),” says Corsten of Uhlmann. “Small, inexpensive, and flexible, the BEC 300 pays tribute to the fact that most pharmaceutical manufacturers are facing the challenge of smaller batch sizes and growing numbers of SKUs. The old recipe of faster and bigger is better, simply doesn’t work anymore.”

New drugs are often more complex, such as large-molecule formulations or cocktail combinations of multiple drugs, notes Stagnaro of Klöckner Pentaplast. “We are also seeing drugs with higher concentrations for once-daily dosing or compounds for slow controlled release,” he says. “As a result, these products often need combined protection against moisture and oxygen.” Klöckner Pentaplast has been responding to this trend by offering high-barrier Aclar laminations, EVOH coextrusions and laminations, and high-crystallinity PVdC coatings.

TOPAS COC has recently been used for “liquid drug storage and biomass delivery in direct contact with body tissue,” reports Barbara Canale, TOPAS Advanced Polymers Inc. “It offers very low leachables and extractables for new drug-delivery applications as well as a unique combination of exceptional purity and excellent molding characteristics.”

Adds Schroeder: “New products coming to market require special handling, particularly large molecule delivery. One area of need is support for cold-chain

logistics. We have invested in significant expansions of our on-site cold storage, with some products even requiring cold rooms for the packaging operation. We have expanded to accommodate more than 800 pallet locations for on-site storage between 2–8°C, with additional storage capacity for products requiring storage down to –20°C.”

Change is also taking place in medical device packaging. “Combination products or hybrid products, such as drug-eluting stents, prefilled syringes, or inhalers, along with kits containing both medical devices and pharmaceutical products, are all driving requests for moisture or oxygen barrier performance and temperature control,” says Justin Glass, business manager, medical device films, Klöckner Pentaplast.

And while downgauging has for some time been a frequent route for taking cost out of packaging, medical device packagers are still pretty cautious, notes Glass. “Of paramount concern is packaging and seal integrity,” he says. “We are working with new polymers offering

## JOIN USP TO TACKLE SUPPLY CHAIN THREATS, EXTRACTABLES AND LEACHABLES

In its next cycle, the Packaging, Storage, and Distribution Expert Committee of the United States Pharmacopeia (USP) will be addressing some of the challenges the pharmaceutical industry is facing in terms of supply-chain management, testing for extractables and leachables, and testing of glass, plastic, and metal container closure systems. The 2010–2015 committee will be led by chair Mary Foster, Pharm.D., vice president of quality for Catalent Pharma Solutions. “There are no written standards yet by FDA or USP in areas such as anti-counterfeiting, technologies for track and trace, supply chain security and risk mitigation practices, as well as for extractables and leachables testing. This USP Expert Committee will take on the challenge of [issuing] collaborative global decisions for new chapters that will provide guidance in these areas,” she

explains. “Companies not already working in these areas will have to be prepared to make critical changes to their processes to ensure the integrity of the products they produce.”

Foster, along with USP staff, has selected 15 members to help create new standard USP General Chapters as well as revise current standards in general chapters. The committee will also continue the work on current chapters under final revisions with feedback from industry such as General Chapter <1079> Good Storage and Transportation Practices. Foster is looking for subject matter experts from around the world that can serve on expert panels to help the committee write new and edit current chapters. “We’ve drawn together experts from industry, academia, and government from around the world, including regulatory agencies such as FDA

as expert committee participants, and expert committee members Health Canada and MHRA, with pharma representation from Canada, Germany, India, United Kingdom, and the United States,” she explains. “We are working in a global supply chain so we wanted a global working group. This USP expert committee will benefit from international input, given such work as Health Canada’s recent supply chain management standards and the IATA Chapter 17 work on air transportation of drug products. We expect this collaboration will be worthy of worldwide acceptance to further [harmonize] standard ways of working across the globe. We just have to get this right for effective and efficient handling of drug products for the U.S. market and consideration for worldwide use.”

USP work has closely followed industry trends, but it is now time to get ahead

better impact strength and the chance for a small amount of downgauging. For instance, there is no question that the new copolyester Tritan [from Eastman Chemical] improves impact strength and heat resistance. But we don't see companies switching to this or other new materials just for the sake of changing. It is being looked at for new products."

### HEALTHCARE CHALLENGES

As nonadherence with pharmaceutical regimens continues to threaten patient outcomes, packaging suppliers continue to develop packaging solutions. "Patient nonadherence in terms of taking and refilling medication is a global concern," says Ruff of Catalent Pharma Solutions. "It is estimated that half of the annual prescriptions dispensed in the United States are not taken as prescribed, and nearly 30% of prescriptions for chronic conditions are not refilled. Poor adherence leads to less than optimal treatment outcomes, which in turn leads to increases in illness, hospital admissions, mortal-

ity, and overall healthcare costs. These trends apply worldwide."

Drug companies are looking for "creative packaging design, particularly around unit-dose child-resistant packaging," says Schroeder. "We are working to take the stigma out of child-resistant packaging by designing packages that are very intuitive and consumer friendly. We have developed several new F = 1 packages that are being very well received in the market. They are all developed to be consumer friendly, cost effective, and designed with sustainability in mind."

Ruff says that Catalent is offering designs "to support patient initiation therapy, titration requirements, and alignment with formulation positioning and Pharmacy-Benefit Management requirements for 30-day supply. We are seeing demand for compliance packages for therapeutic areas such as epilepsy, hypertension, and weight-loss programs."

Even tubes are being designed with compliance-enhancing features. "To emphasize our ongoing commitment

to compliance, we offer an airless tube solution with an exact dosing system for topical applications and we are building a new production line for small diameters fully qualified in clean room ISO 8," reports Richard Misdom, sales manager for Neopac.

However, while "consumer-friendly compliance packaging (CFCP) remains a well-recognized platform, it continues to struggle with cost justification," notes Walter Berghahn for the Healthcare Compliance Packaging Council and Vice President, Packaging Technology, AmerisourceBergen Packaging Group. "This is primarily due to the fact that package providers, quite correctly, are selling the concepts to the pharmaceutical manufacturers, yet the true beneficiaries from improved compliance are at the far end of the supply chain. Ultimately the

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of them, Foster says. For instance, "our intent will be to build upon existing work on the supply chain, but we need guidance to cover the entire contingency as products move from manufacturer to end user," she says. "Up for debate will be whether the guidance will be a mandatory lower chapter or a voluntary higher chapter." A second subject, evaluating packages for extractables and leachables, is not adequately covered to guide industry. "Companies have had to set up their own standard of practice," she continues. "We will bring in experts on glass, elastomers, labeling, desiccants, and any other potential material that could be involved in either an extractable or leachable situation to create a user friendly workable chapter."

A revision of Chapter <1079> was produced late last year, and comments were provided to the previous committee. The new group will be charged with the formation of an expert panel to take those comments and edit the revision as needed.

At Catalent, Foster is responsible for building external relationships with regulatory bodies and pharmacopeia working groups within the pharmaceutical/biotechnology and consumer healthcare industries. She plans to translate recent work Catalent has completed in developing standard processes for measures and accountability into those the expert committee can use to draft new chapters expeditiously.

Over the 2005–2010 USP cycle, Foster provided USP committee updates to industry in the United States, Canada, the EU, and South America and presented at the 2008 and 2009 Annual USP meetings. Foster routinely presents cGMP training courses in the United States, Canada, and EU. She is an Advisory Board member of the International Air Transportation Association (IATA) and a member of the Parenteral Drug Association (PDA) Pharmaceutical Cold Chain Interest Group (PCCIG) committee. Foster has been with Catalent for 20 years having served in various qual-

ity and regulatory roles. Foster's nomination follows shortly after the nomination of Stephen Tindal, Director, Softgel Formulation & Operations for Catalent, to the USP Advisory Panel on Liquid Filled Gelatin Capsules.

Foster encourages any subject matter experts to get involved during this next USP cycle. "We need experts to volunteer for our panels, which could be as short as three to six months or as long as a year. We are setting the standards, writing the definitions and writing the industry guidance (with participation from FDA) so if you are the expert, we need to hear from you," she concludes.

For more information on volunteering to serve as a subject matter expert for the Packaging, Storage, and Distribution Expert Committee, please e-mail Mary Foster at [mary.foster@catalent.com](mailto:mary.foster@catalent.com). For details on the USP 2010–2015 Council of Experts and its Expert Committees, please visit [www.usp.org/goto/councilofexperts](http://www.usp.org/goto/councilofexperts).

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patient is the beneficiary, but one step removed from this is the payer who can obtain economic benefit from improved compliance: healthier patients, improved outcomes, and decreased medical costs.”

The vehicles for providing the payer and health administration community with this economic benefit are beginning to evolve, Berghahn continues. “The most widely known would likely be Medication Therapy Management programs under Medicare Part D. Packaging has not gotten much of a play here primarily because patients needs are assessed one at a time, and CFCP might not be seen as necessary for all individuals in MTM. A great strategy would be to package chronic meds for the three conditions (asthma, diabetes, and heart disease) most likely to show up in the majority of MTM patients.” Other areas that could gain economic benefit from increased patient adherence are Medical Homes programs and Transitions of Care programs, he adds.

Smith of Keystone Folding Box notes that the industry has been closely watching retailer programs involving repackaged generic drugs for low-cost prescription programs. “The industry has been measuring the impact of these programs,” he says. The influence of these programs on new drug packaging decisions remains to be seen, but Smith does see “a lot activity” testing product stability in blisters. “The wheels are in motion; many products in the development pipeline appear to be targeted for unit-dose packaging when launched,” he says.

At FDA’s workshop on developing guidance to reduce the likelihood of medical errors, Kellie Taylor, who serves as associate director for FDA’s Division of Medication Error Prevention and Analysis in the Office of Surveillance and Epidemiology, told the audience that “33 percent of medication error reports to the [Institute of Safe Medication Practices; ISMP] Medication Error Reporting Program may be attributed to packaging and labeling of drug products, including about 30 percent of all fatal errors.”

Suppliers offered solutions. “Actually, we participated in this FDA workshop,” says Gene Dul, president of Schreiner MediPharm LP. “We have been aware of the importance of clear drug labeling and identification for many years and have addressed this issue by developing sophisticated labeling solutions that help prevent medication errors. Easy and fast drug administration combined with patient safety is one of the key objectives when developing our labels.” For instance, the company has developed Pharma-Comb labels with one or several detachable parts that can help clearly identify the drug, all the way from dispensing to patient administration. Detachable parts automatically rise after opening the outer label and can be easily and quickly applied to filled disposable syringes after drawing a dose from the vial.”

“It is a quite exciting time for the packaging community,” concludes Berghahn. “The opportunity to contribute to the solution of improved healthcare is quite real and evolving as we watch.” ■